FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

Selection Criteria:

Product Name:	.;ACTHAR GEL-SYNTHETIC
Product Active Ingredient:	.
Active Ingredient	.;CORTICOTROPIN
Active Moiety:	.
FDA Received Date:	From: 01-JAN-2001 To: 05-MAY-2014
MedDRA® Version* :	17.0
Total Cases**:	243
Number of Pages:	121

Disclaimer: Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

*. “MedDRA® Version” refers to the name and version of the dictionary in use at the time the cases were retrieved from the FDA Adverse Event Reporting System (FAERS). MedDRA Medical Dictionary for Regulatory Activities (MedDRA®) is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to code adverse events, medication errors and other information associated with the use of medical products. A MedDRA® Preferred Term (PT) is used to standardize a “medical concept” in a report. For example, a report of “heart attack” or “myocardial infarct” are standardized to the same Preferred Term, “Myocardial Infarction”. MedDRA is updated twice a year.

**. “Total Cases” reflects the number of individual patient case reports associated with the product of interest that were submitted to FDA within the specified time period. A case consists of an initial report and any follow-up reports submitted to FDA. Because FDA may receive reports on the same patient from more than one source, some of these cases may be duplicate patient reports.

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The information in this report is generated from the FDA Adverse Event Reporting System (FAERS) by using a report query where suspect product(s) or active ingredients are selected from a standardized dictionary and a date range is specified as search criteria. The table below provides the definitions for field headings that are listed on the report.

FAERS data have limitations, including the following. There is no certainty that the reported event was actually due to the product. Reports are often incomplete - a blank field means that no data were provided. FDA does not receive reports on all adverse events that occur with a product. Many factors can influence whether or not an event will be reported, therefore, FAERS data cannot be used to compare products or calculate how frequently an event occurs in the U.S. population.

Field Heading	Definition
FDA Received Date	The date that FDA received the most recent information regarding a case, either as an initial report or follow-up report. The FDA Received Date may not be the same as the date that the event occurred. The event may have occurred days or even months (or years) before the report was sent to (and received by) FDA. Note the displayed date on the report may be later than the query date range if FDA received follow-up information for a case. FDA provides the most current case information available.
Case #	A unique number assigned by FDA that identifies a FAERS case. A case includes the information received in the initial report plus any additional information received in follow-up reports.
Case Type	There are three case types in FAERS: Expedited (15-Day): submitted to FDA by manufacturers; these are reports containing serious, unexpected adverse events Nonexpedited: submitted periodically to FDA by manufacturers; these are reports containing adverse events other than those qualifying for expedited (15-day) reporting Direct: submitted “directly” to FDA by healthcare professionals, patients and other consumers
Health Professional	Indicates whether the initial source who provided information about the event is a health professional (HP). Possible values are; Y - Yes, N – No or the field is blank if it was not reported
Outcomes	Based on FDA regulations, the reported outcome(s) determines whether a case is serious. The outcome categories include congenital anomaly/birth defect (CA), death (DE), disability (DS), hospitalization (HO), life-threatening (LT), other serious important medical event (OT), and required intervention to prevent permanent impairment/damage (RI). A case can have more than one outcome.
Manufacturer Control #	The Manufacturer Control Number is the manufacturer’s unique identifier associated with the case. Also referred to as the Company Report Number.
Age	The patient's age, with age unit, based on information provided in the report.
Sex	Patient sex (Male, Female, Unknown).
Country	The country where the event occurred. If not reported, then the country of the reporter. The International Organization for Standardization (ISO) 3166-1 alpha-3 country code is used as an abbreviation for the country.

Field Heading	Definition
Preferred Term	A Medical Dictionary for Regulatory Activities (MedDRA®) Preferred Term (PT) is used to standardize a “medical concept” in a report. For example, a report of “heart attack” or “myocardial infarct” are standardized to the same Preferred Term, “Myocardial Infarction”. MedDRA is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to “code” adverse events, medication errors and other information associated with the use of medical products
Product	Name of a drug or therapeutic biologic in the case report. A product name can appear as either a brand name (trade name) or an active ingredient name, depending on what was reported.
Role	There are two roles for products listed on the cases. Suspect (S) identifies the product(s) that the initial reporter deemed most likely to be associated with the event. Concomitant (C) identifies products taken at the same time as the suspect product, but not deemed by the initial reporter as being associated with the event.
Route	Reported route of product administration (e.g., oral, topical, injection, sublingual, inhalation).
Dosage Text	Refers to the amount of the product that was taken or given to a patient, and the frequency of administration. For example, 20 mg twice daily.
Duration	The length of time the product was used. For example, if someone reported taking Drug A from January 1 to January 30, the duration would be 30 days.
Manufacturer	The manufacturer of the product, as indicated in the report.

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2001	3685007	NON-EXPEDITED		HO	200111642US		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nausea	H.P. ACTHAR	S		QW		AVENTIS
Flushing	CORTICOTROPIN	S		1 CC QW	30 YR	
Conjunctival hyperaemia	NO INGREDIENT DEFINED (CARDIOVASCULAR SYSTEM) POTASSIUM	C				
Erythema	POTASSIUM	C				
Diarrhoea						
Electrolyte imbalance						
Eye irritation						
Eyelid oedema						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jan-2002	3751110	EXPEDITED (15-DAY)	Y		M0832-2001	57 YR	Female	ITA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Injection site erythema	CORTICOTROPIN	S				
Injection site nodule						
Injection site pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jul-2002	3858319	NON-EXPEDITED	N	HO,RI	ACT-S0001	1 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cardiomyopathy	H.P. ACTHAR	S	INTRAMUSCULAR	30 IU QOD IM		
Hypertension						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2002	3871217	EXPEDITED (15-DAY)	Y	HO,OT	ZONI000947	5 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Decreased appetite	ZONEGRAN	S	ORAL	150 MG DAILY ORAL		
Calculus urinary	ACTH	S		.025 MG/KG DAILY		
Convulsion	PROPRANOLOL	C				
Electroencephalogram abnormal	VALPROATE SODIUM	C				
Flat affect	CLONAZEPAM	C				
Haematuria						
Laboratory test abnormal						
Pyelocaliectasis						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Apr-2003	3942399	DIRECT	Y	DE		319 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Respiratory arrest	ACTH	S		40 DOSE UNITS/ DAY INJECTION		
Vomiting	TRIMETHOPRIM/ SULFAMETHOXAXZOLE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Apr-2003	3942472	DIRECT	Y	DE		1 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	ACTH	S		60 DOSE UNITS/DAY INJECTIONS		QUESTCOR
Hypertension	PYRIDOXINE HYDROCHLORIDE	C				
Respiratory arrest	SULFAMETHOXAZOLE AND TRIMETHOPRIM	C				
	DIURIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-May-2003	3951730	DIRECT	Y	HO,RI		91 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure increased	CORTICOTROPIN	S	INTRAMUSCULAR	20 IU QOD INTRAMUSCULAR		
Cardiac disorder						
Cardiac murmur						
Hypertrophic cardiomyopathy						
Ventricular hypertrophy						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Jun-2003	3955320	EXPEDITED (15-DAY)	Y	DE	03-ADE-SU-0002-ACT	304 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Coma	H.P. ACTHAR	S	INTRAMUSCULAR	40 UNITS QOD IM		QUESTCOR
Congenital central nervous system anomaly	BACTRIM	C				
Congenital cardiovascular anomaly						
Respiratory arrest						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Aug-2003	3955318	EXPEDITED (15-DAY)	Y	DE	03-ADE-SU-0001-ACT	1 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	ACTHAR	S	INTRAMUSCULAR	32 U/ML QOD IM		QUESTCOR
Respiratory arrest	BACTRIM	C				
Sudden death	DIURIL	C				
	PYRIDOXINE HYDROCHLORIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Aug-2003	3965651	EXPEDITED (15-DAY)	Y	HO	03-ADE-SU-0003-ACT	52 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure increased	ACTHAR	S	INTRAMUSCULAR	40 UNNITS QD IM		QUESTCOR
Cerebral haemorrhage	SUDAFEDRINE, NEURONTIN	C				
Delirium tremens	DURGESIC PATCHES	C				
Tremor	KLONOPIN	C				
	PROVIGIL	C				
	PROZAC	C				
	NEURONTIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Sep-2004	4212236	EXPEDITED (15-DAY)		OT	234313K04USA	43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Injection site cellulitis	REBIF	S		44 MCG, 3 IN 1 WEEKS		
Injection site necrosis	ACTH	S	INTRAMUSCULAR	INTRA-MUSCULAR		
Injection site pain						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Dec-2004	5662140	EXPEDITED (15-DAY)	Y	HO,LT	PHBS2004JP14919	60 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pulmonary oedema	NEORAL	S	ORAL	50 mg/d	1144 DAY	NOVARTIS
Lung disorder	PREDNISOLONE	S	UNKNOWN	5 mg/d	1144 DAY	
Systemic inflammatory response syndrome	CORTICOTROPIN	S	INTRAVENOUS	10 mg/d		
Pneumonia	MIZORIBINE	C	ORAL	100 mg/d	1144 DAY	
Hypoxia	MIZORIBINE	C	ORAL	100 mg/d		
Blood creatinine increased						
Blood urea increased						
Breath sounds abnormal						
Cardiomegaly						
C-reactive protein increased						
Dyspnoea						
Haemodialysis						
Life support						
Nasopharyngitis						
Orthopnoea						
Pyrexia						
Renal impairment						
Urine output decreased						
White blood cell count increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Apr-2005	5781499	EXPEDITED (15-DAY)	Y	HO	05P-163-0296286-00	4 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sepsis	DEPAKENE	S				
Hypertension	CORTICOTROPIN	S				
Blood pressure immeasurable						
Candida infection						
Pancreas infection						
Pancreatitis haemorrhagic						
Pseudocyst						
Pulmonary oedema						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Apr-2005	5774971	EXPEDITED (15-DAY)		HO	PHBS2005JP04886	50 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pneumonia cryptococcal	CICLOSPORIN	S	UNKNOWN			NOVARTIS
Pyrexia	CORTICOTROPIN	S	UNKNOWN			
Blood beta-D-glucan increased						
Fungal test positive						
Inflammation						
Lung infiltration						
Pneumomediastinum						
Respiratory disorder						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Jun-2005	5826381	EXPEDITED (15-DAY)	N	HO	138768USA	42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	COPAXONE	S				
Nervousness	ACTHAR GEL-SYNTHETIC	S				
Irritability	WELLBUTRIN	C				
Depression	TRILEPTAL	C				
Suicidal ideation	ZANAFLEX	C				
Steroid withdrawal syndrome	PROVIGIL	C				
Multiple sclerosis	SYNTHROID	C				
Condition aggravated	ATENOLOL	C				
	REMERON	C				
	TRAZODONE HYDROCHLORIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jan-2006	5966070	DIRECT	Y	DS		152 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertrophic cardiomyopathy	CORTICOTROPIN	S	INTRAMUSCULAR	50 UNITS DAILY IM		
Hypertension						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2006	6097761	DIRECT	Y	HO		2 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pyrexia	RITUXIMAB	S	INTRAVENOUS	375 MG/M2 IV X 4		
Vomiting	CORTICOTROPIN	S	INTRAMUSCULAR	0.12 CC IM QOD		
Drug intolerance						
Escherichia urinary tract infection						
Hypophagia						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Aug-2006	6116280	EXPEDITED (15-DAY)	Y	HO	ADE-SU-0013-ACT	32 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	H.P. ACTHAR	S		80 IU IM QD WITH TAPER		
Hypertension	AVONEX	C				
	LEXAPRO	C				
	ATIVAN	C				
	ZANAFLEX	C				
	LYRICA	C				
	LABETALOL HCL	C				
	VESICARE	C				
	METHOTREXATE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Aug-2006	6090243	EXPEDITED (15-DAY)	Y	DE,HO,OT	PHBS2006JP10464	20 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Staphylococcal infection	NEORAL	S	ORAL	150 mg/d		NOVARTIS
Multi-organ failure	CORTICOTROPIN	S	ORAL	20 mg/d		
Sepsis	PENTASA	C		20 mg/d		
Anaemia						
Back pain						
Blood pressure decreased						
Chest pain						
Coagulation time prolonged						
Depressed level of consciousness						
Epistaxis						
Haematochezia						
Hepatic enzyme increased						
Hepatic failure						
Hepatic function abnormal						
Hepatocellular injury						
Herpes zoster						
Melaena						
Oliguria						
Platelet count decreased						
Shock						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Sep-2006	6139409	EXPEDITED (15-DAY)	Y	HO	06-ADE-SU-0017-ACT	213 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Herpes simplex meningoencephalitis	CORTICOTROPIN	S	INTRAMUSCULAR	150 U/M2 PER DAY IM	10 DAY	
Disease recurrence	COPAXONE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Oct-2006	6152650	DIRECT	Y	OT		1 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vomiting	ACTH	S		80 UNITS/ML DAILY		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2007	6233490	EXPEDITED (15-DAY)	N	HO	06-ADE-SU-0029-ACT	41 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myalgia	H.P. ACTHAR	S	INTRAMUSCULAR	80 U IM QD		
Muscle spasms	AVONEX	C				
Body temperature increased						
Drug effect decreased						
Drug ineffective						
Injection site cellulitis						
Injection site reaction						
Localised infection						
Nuclear magnetic resonance imaging abnormal						
White blood cell count increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jun-2007	6324100	EXPEDITED (15-DAY)	Y	OT	PHBS2007IT08693	19 YR	Male	ITA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypokalaemia	OXCARBAZEPINE	S				NOVARTIS
Hyperglycaemia	ACTH	S		0.01 mg/kg/day		
Glycosuria	PRIMIDONE	S				
Fluid retention	VALPROATE SODIUM	S				
Drug ineffective						
Drug interaction						
Drug level decreased						
Epilepsy						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jul-2007	6378493	NON-EXPEDITED	Y	HO	QST_00027_2007	51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cardiac failure congestive	H.P. ACTHAR	S	INTRAMUSCULAR	(1 DF QD INTRAMUSCULAR)		
	LISINOPRIL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jul-2007	6378494	NON-EXPEDITED	N	OT	QST_00014_2007	38 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Oral candidiasis	H.P. ACTHAR	S	SUBCUTANEOUS	(80 IU QD X1 WEEK, FOLLOWED BY TAPER SUBCUTANEOUS)		
	AVONEX	C				
	BACLOFEN	C				
	NEURONTIN	C				
	VESICARE	C				
	ZANAFLEX	C				
	KLONOPIN	C				
	HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Sep-2007	6426551	EXPEDITED (15-DAY)		HO	07-ADE-SU-0012-ACT	109 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Irritability	H.P. ACTHAR	S	INTRAMUSCULAR	40U IM QD		
Cold sweat	VIGABATRIN	C				
Complex partial seizures						
Condition aggravated						
Convulsion						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Feb-2008	6579397	EXPEDITED (15-DAY)	Y	HO	CIP08000267		Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Purulence	RISEDRONATE SODIUM	S	ORAL	17.5 MG, 1/WEEK, ORAL		
Pulpitis dental	CORTICOTROPIN	S				
	ELCITONIN (ELCATONIN)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Apr-2008	6617712	EXPEDITED (15-DAY)	N	HO	08-ADE-SU-0003-ACT	334 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Acne	ACTHAR	S		40 IU IM QD WITH TAPER		
Fluid retention	CLONAZEPAM 0.2 MG	C				
Weight increased	VITAMIN B	C				
Chromaturia						
Decreased appetite						
Dehydration						
Diet refusal						
Hypophagia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Apr-2008	6618820	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2008032792	39 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Phaeochromocytoma	HYDROCORTISONE SODIUM SUCCINATE	S	PARENTERAL			
Myocardial ischaemia	PREDNISONE	S	ORAL			
Cardiac failure congestive	ACTH	S				
Aspartate aminotransferase increased						
Hypertension						
Hyperthermia						
Pulmonary oedema						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jun-2008	6729230	NON-EXPEDITED	N	HO	08-ADE-SE-0002-ACT	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Wheezing	H.P. ACTHAR	S		40 U TWICE WEEKLY		
Multiple sclerosis relapse						
Pneumonia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jul-2008	6697029	EXPEDITED (15-DAY)	Y	LT	US-WATSON-2008-03941	39 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Phaeochromocytoma	HYDROCORTISONE ACETATE	S	PARENTERAL	UNK		WATSON
	PREDNISONE	S	ORAL	UNK		WATSON
	ACTH	S	PARENTERAL	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Aug-2008	6719085	EXPEDITED (15-DAY)	Y	OT	US-BOEHRINGER INGELHEIM GMBH, GERMANY-2008-BP-12011RO	334 DAY	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypercalcaemia	PREDNISONE	S				BOEHRINGER INGELHEIM
	ACTH	S				
	CALCIUM	S				
	REHYDRATION	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Aug-2008	6738271	EXPEDITED (15-DAY)	Y	HO	US-WATSON-2008-05026	334 DAY	Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypercalcaemia	PREDNISONE	S	UNKNOWN	12 mg, bid with 4 week taper		WATSON
Withdrawal syndrome	PREDNISONE	S	UNKNOWN	3 mg, bid		WATSON
	ACTH	S	UNKNOWN	UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Aug-2008	6753599	EXPEDITED (15-DAY)	Y	HO	2007-01039FE		Unknown	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pituitary haemorrhage	CORTICOTROPIN	S	INTRAVENOUS	20 MCG ONCE		
Headache	GONADORELIN	S	INTRAVENOUS	20 MCG ONCE		
Nausea	GONADORELIN	S	INTRAVENOUS	20 MCG ONCE		
Chest discomfort	THYROTROPIN	S	INTRAVENOUS	100 MCG ONCE		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Aug-2008	6754753	EXPEDITED (15-DAY)	Y	HO	2007-01098FE	67 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pituitary haemorrhage	GONADORELIN	S			1 DAY	
Headache	CORTICOTROPIN\SERACTIDE ACETATE	S			1 DAY	
Haematoma						
Neoplasm progression						
Nerve compression						
Nuclear magnetic resonance imaging abnormal						
Visual impairment						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Aug-2008	6758690	EXPEDITED (15-DAY)	Y	HO,OT	2007-01070FE	49 YR	Male	DEU

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blindness	PROTIRELIN	S	INTRAVENOUS	0.2 MG ONCE IV		
Headache	GONADORELIN	S	INTRAVENOUS	0.1 MG ONCE IV		
Nausea	ACTH	S	INTRAVENOUS	0.25 MG ONCE IV		
Vision blurred						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Oct-2008	6745808	EXPEDITED (15-DAY)	Y	OT	JP-GENENTECH-267008	72 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
VIIth nerve paralysis	RITUXAN	S				GENENTECH
	CYCLOPHOSPHAMIDE	S				
	ADRIAMYCIN	S				
	PREDNISOLONE	S				
	CORTICOTROPIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-May-2009	6994519	EXPEDITED (15-DAY)	Y	DE	09-ADE-SU-0013-ACT	136 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Bronchiolitis	ACTH	S	INTRAMUSCULAR	ACTH 20-40 U IM QD		
Acute respiratory distress syndrome	PHENOBARBITAL	C				
Tonic convulsion	CEFACLOR	C				
Diarrhoea						
Infantile spasms						
Irritability						
Oral candidiasis						
Pneumonia						
Pulmonary oedema						
Respiratory failure						
Respiratory syncytial virus test positive						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-May-2009	8584439	EXPEDITED (15-DAY)	Y	OT	09-ADE-SU-0011-ACT	7 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Leukaemia	H.P. ACTHAR	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Oct-2009	7171596	EXPEDITED (15-DAY)		DE	09-ADE-SU-0027-ACT	136 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pneumonia aspiration	H.P. ACTHAR	S		40 IU/DAY WITH TAPER		
Somnolence	PHENOBARBITAL	C				
Irritability	LANSOPRAZOLE	C				
	METOCLOPRAMIDE	C				
	GLYCOPYRROLATE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Dec-2009	7225795	EXPEDITED (15-DAY)	Y	HO	09-ADE-SU-0032-ACT	70 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Urine output decreased	H.P. ACTHAR	S		80 U SC X 5 D THEN TAPER	10 DAY	
Cardiac failure congestive						
Dyspnoea						
Oedema peripheral						
Urinary tract infection						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Dec-2009	7228400	EXPEDITED (15-DAY)	N	HO	09-ADE-SU-0034-ACT	243 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Respiratory tract infection	H.P. ACTHAR	S	SUBCUTANEOUS	80 U SC BID - 6 WK TAPER		
Hypertension	PHENOBARBITAL	C				
Decreased appetite						
Diet refusal						
Weight increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Dec-2009	7229292	EXPEDITED (15-DAY)	N	HO	09-ADE-SU-0033-ACT	243 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Weight increased	H.P. ACTHAR	S		80 U SC BIS - 6 WK TAPER		
Decreased appetite	PHENOBARBITAL	C				
Diet refusal						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Dec-2009	7229057	DIRECT	Y	DE,HO,LT,OT		2 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Septic shock	RITUXIMAB	S	INTRAVENOUS DRIP	750 MG/M2 2X, 2 WKS APART IV DRIP		GENENTECH
Multi-organ failure	ACTHAR GEL-SYNTHETIC	S	INTRAMUSCULAR	25 IU/M2 QOD IM		QUESTCOR
Aplastic anaemia	CLONIDINE	C				
Hydrocephalus	AMLODIPINE	C				
Cerebral haemorrhage	CALCIUM CARBONATE	C				
Convulsion	CAPTOPRIL	C				
Renal failure acute	NIFEDIPINE	C				
Acute respiratory distress syndrome	HUMAN IMMUNOGLOBULIN G	C				
Hypertension	BACTRIM	C				
Sepsis	PENTAMIDINE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Mar-2010	8584444	EXPEDITED (15-DAY)	N	HO	09-ADE-NU-0006-ACT	4 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cushing's syndrome	H.P. ACTHAR	S	INTRAMUSCULAR	0.28 ML QOD IM		
Adrenomegaly	HUMAN IMMUNOGLOBULIN G	C				
	BACTRIM	C				
	PREVACID	C				
	RITUXIMAB	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Apr-2010	7344588	EXPEDITED (15-DAY)	Y	OT	JP-PFIZER INC-2010042681		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Stereotypy	METHYLPREDNISOLONE	S				PFIZER
	CORTICOTROPIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Apr-2010	7361103	EXPEDITED (15-DAY)	N	HO	233212J10USA	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood glucose increased	REBIF	S				
Blood potassium abnormal	CORTICOTROPIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-May-2010	7407829	EXPEDITED (15-DAY)	Y	HO	10-ADE-SU-0020-ACT	70 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dizziness	H.P. ACTHAR	S	SUBCUTANEOUS	80 IU SC QD X 5 DAYS		
Nausea	REBIF	C				
Fall	ASA	C				
Treatment noncompliance						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jun-2010	7423952	EXPEDITED (15-DAY)	Y	DE	10-ADE-SU-0024-ACT		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Neonatal infection	H.P. ACTHAR	S			6 YR	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jun-2010	7424176	EXPEDITED (15-DAY)	Y	DE	10-ADE-SU-0025-ACT		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Infection	H.P. ACTHAR	S		10 YEARS AGO		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jul-2010	7537469	NON-EXPEDITED	Y	HO	09-ADE-SE-0040-ACT	75 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cardiac failure congestive	H.P. ACTHAR	S		40 IU IM Q3D		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jul-2010	7537521	NON-EXPEDITED	Y	HO	09-ADE-SE-0019-ACT		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Herpes zoster	H.P. ACTHAR	S				
	KLONOPIN	C				
	ZONISAMIDE	C				
	PREDNISONE	C				
	VITAMIN B6	C				
	MELATONIN	C				
	VIGABATRIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jul-2010	7537524	NON-EXPEDITED	N	HO	09-ADE-SE-0017-ACT	213 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	H.P. ACTHAR	S		.53 ML IM BID WITH TAPER		
Glaucoma	SEPTRA - TIW	C				
Oedema peripheral	VIGABATRIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Jul-2010	7537534	NON-EXPEDITED	N	HO	09-ADE-SE-0015-ACT	3 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	H.P. ACTHAR	S		40 IU IM BID WITH TAPER		
Kyphosis						
Muscular weakness						
Osteoporosis						
Spinal compression fracture						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jul-2010	7503051	DIRECT	Y	HO,OT		255 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	CORTICOTROPIN	S	INTRAMUSCULAR	32 UNITS IM		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Aug-2010	7547161	EXPEDITED (15-DAY)	Y	OT	DE-JNJFOC-20100805590	3 YR	Female	DEU

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug resistance	TOPAMAX	S	UNKNOWN			
	VALPROIC ACID	S	UNKNOWN			
	CLOBAZAM	S	UNKNOWN			
	PYRIDOXINE HYDROCHLORIDE	S	UNKNOWN			
	SULTHIAME	S	UNKNOWN			
	PHENOBARBITAL	S	UNKNOWN			
	CORTICOTROPIN	S	UNKNOWN			
	VIGABATRIN	S	UNKNOWN			
	LEVETIRACETAM	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Oct-2010	7369418	EXPEDITED (15-DAY)	Y	HO	PHHY2010JP24881	13 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tracheostomy malfunction	NEORAL	S	ORAL	80 mg daily	1 DAY	NOVARTIS
Lung operation	NEORAL	S	ORAL	700 mg daily	16 DAY	NOVARTIS
Bronchostenosis	NEORAL	S	ORAL	300 mg daily	17 DAY	NOVARTIS
Laser therapy	NEORAL	S	ORAL	280 mg daily	39 DAY	NOVARTIS
Tracheostomy	NEORAL	S	ORAL	200 mg daily	28 DAY	NOVARTIS
Pulmonary artery therapeutic procedure	NEORAL	S	ORAL	300 mg daily		NOVARTIS
	SANDIMMUNE	S	INTRAVENOUS	12 mg daily	3 DAY	
	SANDIMMUNE	S	INTRAVENOUS	24 mg daily	2 DAY	
	SANDIMMUNE	S	INTRAVENOUS	60 mg daily	15 DAY	
	CORTICOTROPIN	S	INTRAVENOUS	1000 mg daily	1 DAY	
	CORTICOTROPIN	S	INTRAVENOUS	250 mg daily	1 DAY	
	CORTICOTROPIN	S	INTRAVENOUS	40 mg daily	2 DAY	
	CORTICOTROPIN	S	INTRAVENOUS	20 mg daily	18 DAY	
	CORTICOTROPIN	S	ORAL	12.5 mg daily	89 DAY	
	CORTICOTROPIN	S	ORAL	10 mg daily	22 DAY	
	CORTICOTROPIN	S	ORAL	7.5 mg daily	203 DAY	
	CORTICOTROPIN	S	ORAL	6.25 mg daily		
	MYCOPHENOLATE MOFETIL	S	ORAL	250 mg daily	1 DAY	
	MYCOPHENOLATE MOFETIL	S	ORAL	500 mg daily	250 DAY	
	MYCOPHENOLATE MOFETIL	S	ORAL	750 mg daily		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Oct-2010	7599471	EXPEDITED (15-DAY)	Y	DE	10-ADE-SU-0045-ACT	1 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pneumonia	H.P. ACTHAR	S	INTRAMUSCULAR	80 IU IM WITH TAPER		
Respiratory distress	CLOBAZAM	C				
	VIGABATRIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jan-2011	7778562	EXPEDITED (15-DAY)	Y	HO	10-ADE-SU-0068-ACT	35 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Grand mal convulsion	H.P. ACTHAR	S		80 IU SC DAILY X 5 DAYS		
White blood cell count decreased	REBIF	C				
Blood potassium decreased	KLONOPIN	C				
Blood sodium increased	PROMETHAZINE	C				
Hypertension	PROZAC	C				
Adrenal disorder	ZOCOR	C				
	BACLOFEN	C				
	ZANAFLEX	C				
	COUMADIN	C				
	AGRYLIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jan-2011	8584445	DIRECT	Y	OT		237 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
No therapeutic response	H.P. ACTHAR	S	INTRAMUSCULAR	0.6ML QAM IM		QUESTCOR
Developmental delay						
Product counterfeit						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Feb-2011	7795613	EXPEDITED (15-DAY)	Y	HO,OT	US-BAYER-200810735NA	43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Multiple sclerosis relapse	INTERFERON BETA-1B	S	SUBCUTANEOUS	8 miu, QOD	29 DAY	BAYER
Muscular weakness	INTERFERON BETA-1B	S		UNK	100 DAY	BAYER
Pain in extremity	INTERFERON BETA-1B	S		UNK	386 DAY	BAYER
Dizziness	INTERFERON BETA-1B	S	SUBCUTANEOUS	2 miu, QOD	561 DAY	BAYER
Headache	INTERFERON BETA-1B	S	SUBCUTANEOUS	8 miu, QOD	9 DAY	BAYER
Angiopathy	INTERFERON BETA-1B	S	SUBCUTANEOUS	8 miu, QOD	3 DAY	BAYER

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Nervous system disorder	INTERFERON BETA-1B	S		6 miu, QOD		BAYER
Contusion	ACTHAR	S				
Intervertebral disc degeneration	ACTHAR	S				
Neck pain	FAMOTIDINE	C				
Blindness unilateral	PREDNISONE	C		TAPERING TO 40 MG		
Central nervous system inflammation	UNCODEABLE "UNCLASSIFIABLE"	C				
Photophobia	PERCOCET	C				
Abdominal discomfort						
Abdominal pain upper						
Abnormal sensation in eye						
Aphagia						
Back pain						
Balance disorder						
Blood pressure decreased						
Central nervous system lesion						
Cerebrovascular arteriovenous malformation						
Dyspepsia						
Erythema						
Eye pain						
Eye swelling						
Fall						
Flushing						
Gastrooesophageal reflux disease						
Haematemesis						
Headache						
Head discomfort						
Heart rate decreased						
Malaise						
Nausea						
Optic nerve injury						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Oropharyngeal pain						
Oxygen saturation decreased						
Pharyngeal oedema						
Pupils unequal						
Skin injury						
Stress						
Visual acuity reduced						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Feb-2011	7794864	EXPEDITED (15-DAY)	Y	DE,HO,OT	PHHY2011JP06959	70 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hepatitis E	SANDIMMUNE	S	INTRAVENOUS	UNK		NOVARTIS
Hepatitis fulminant	CORTICOTROPIN	S	INTRAVENOUS			
Hepatic atrophy	STEROIDS NOS	C				
Adrenalitis						
Alanine aminotransferase increased						
Aspartate aminotransferase increased						
Blood bilirubin increased						
Cholestasis						
Condition aggravated						
Cytomegalovirus infection						
Eosinophilic pneumonia						
Haemorrhage						
Hepatic fibrosis						
Hepatic function abnormal						
Hepatic necrosis						
Jaundice						
Pancreatitis necrotising						
Pneumonia						
Prothrombin time prolonged						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Mar-2011	7890138	EXPEDITED (15-DAY)	Y	HO	11-ADE-SU-0020-ACT	1 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hyperthermia malignant	H.P. ACTHAR	S		30 IU IM BID WITH TAPER		
	ALBUTEROL	C				
	VALPROIC ACID	C				
	ZANTAC	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Apr-2011	7932776	DIRECT	Y	OT		32 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mobility decreased	ACTHAR	S	SUBCUTANEOUS	80 U DAILY SC		QUESTCOR
Abasia						
Diplopia						
Dysgeusia						
Impaired driving ability						
Thinking abnormal						
Vision blurred						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Apr-2011	7575889	EXPEDITED (15-DAY)	Y	HO,LT,OT	PHHY2010JP56543	22 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Lymphoma	CICLOSPORIN	S		80 mg, BID	33 DAY	NOVARTIS
Tongue neoplasm malignant stage unspecified	CICLOSPORIN	S		80 mg	35 DAY	NOVARTIS
Malnutrition	CICLOSPORIN	S		50 mg	413 DAY	NOVARTIS
Urine ketone body present	CICLOSPORIN	S		UNK		NOVARTIS
Respiratory failure	NEORAL	S	ORAL	UNK	17 DAY	
Dyspnoea	SANDIMMUNE	S	INTRAVENOUS DRIP	UNK	12 DAY	
Vital capacity decreased	MYCOPHENOLATE MOFETIL	S	ORAL	250 mg, UNK	1 DAY	
Hypophagia	MYCOPHENOLATE MOFETIL	S	ORAL	500 mg, UNK	8 DAY	
Tachycardia	MYCOPHENOLATE MOFETIL	S	ORAL	750 mg, UNK	40 DAY	
Blood pressure decreased	MYCOPHENOLATE MOFETIL	S	ORAL	500 mg, UNK	125 DAY	
Blood creatinine increased	MYCOPHENOLATE MOFETIL	S	ORAL	750 mg, UNK		
Hypoglycaemia	METHYLPREDNISOLONE	S	INTRAVENOUS	100 mg, UNK	9 DAY	
Gastroenteritis	METHYLPREDNISOLONE	S	INTRAVENOUS	50 mg, UNK	6 DAY	
Diarrhoea	PREDNISOLONE	S	ORAL	15 mg, UNK		
White blood cell count increased	PREDNISOLONE	S	ORAL	12.5 mg, UNK		
Metabolic acidosis	PREDNISOLONE	S	ORAL	10 mg, UNK		
Dehydration	PREDNISOLONE	S	ORAL	7.5 mg, UNK		

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Enterocolitis	PREDNISOLONE	S	ORAL	6.75 mg, UNK		
Nausea	PREDNISOLONE	S	ORAL	5 mg, UNK		
	PREDNISOLONE	S	ORAL	3.75 mg, UNK		
	PREDNISOLONE	S	ORAL	5 mg, UNK		
	CORTICOTROPIN	S	INTRAVENOUS	1500 mg, UNK		
	HYDROCORTISONE SODIUM SUCCINATE	C	INTRAVENOUS	100 mg		
	METILDIGOXIN	C		0.1 mg/day		
	ETIZOLAM	C		1 mg/day		
	SULFAMETHOXAZOLE AND TRIMETHOPRIM	C		1 g/day		
	AMPHOTERICIN B	C		1.2 g/day		
	ACYCLOVIR	C		200 mg/day		
	LANSOPRAZOLE	C		60 mg/day		
	ATROPINE SULFATE	C		0.3 mg		
	PETHIDINE HYDROCHLORIDE	C	INTRAMUSCULAR	30 mg		
	MIDAZOLAM	C		2 mg		
	PROPOFOL	C		40 mg		
	REMIFENTANIL	C		0.25 ug/kg/min		
	SEVOFLURANE	C		03 percent		
	ROCURONIUM BROMIDE	C		20 mg		
	CEFAZOLIN SODIUM	C	INTRAVENOUS	600 mg		
	VALGANCICLOVIR	C	ORAL	450 mg, UNK	29 DAY	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2011	8034315	NON-EXPEDITED	Y	HO	10-ADE-SE-0056-ACT	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Oedema	H.P. ACTHAR	S				
Fluid retention						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2011	8034320	NON-EXPEDITED	Y	HO	10-ADE-SE-0027-ACT	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Multiple sclerosis relapse	H.P. ACTHAR	S	SUBCUTANEOUS	80 IU SC DAILY X 5 DAYS		
Hypokalaemia	PROVIGIL	C				
Oedema peripheral	SYNTHROID	C				
	LASIX	C				
	HYOSCYAMINE	C				
	PROTONIX	C				
	SIMVASTATIN	C				
	PRISTIQ EXTENDED RELEASE	C				
	XANAX	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jun-2011	7399061	EXPEDITED (15-DAY)	Y	HO	10-ADE-SU-0016-ACT	213 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cardiomyopathy	H.P. ACTHAR	S		30IU IM Q12H		
Pneumothorax	TOPAMAX	C				
Pneumocystis jirovecii pneumonia	ZONEGRAN	C				
Pneumonia streptococcal	VIGABATRIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
30-Jun-2011	7743925	EXPEDITED (15-DAY)	Y	DE	10-ADE-SU-0065-ACT	2 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sepsis	H.P. ACTHAR	S		34 IU IM BID TO QOD		
Pancytopenia	RITUXAN	C				
Hypotension	HYDROCORTISONE	C				
Bone marrow failure						
Cardiac output decreased						
Drug ineffective						
Haemorrhage intracranial						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Jul-2011	8019627	EXPEDITED (15-DAY)	Y	OT	PHHY2009JP45379	20 YR	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cytomegalovirus infection	SIMULECT	S		20 mg, UNK		NOVARTIS
Transplant rejection	TACROLIMUS	S	ORAL	UNK		
Pneumocystis jirovecii pneumonia	CORTICOTROPIN	S	ORAL	UNK		
	METHYLPREDNISOLONE	S		UNK		
	MYCOPHENOLATE MOFETIL	S	ORAL	UNK		
	RITUXIMAB	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Aug-2011	8085942	EXPEDITED (15-DAY)	Y	HO,LT	2011MA009088	1 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Toxicity to various agents	PHENOBARBITAL	S	RECTAL	30 MG/KG;QD;RTL		
Drug ineffective	VITAMIN B6	S				
Salivary hypersecretion	HUMAN IMMUNOGLOBULIN G	S				
Obstructive airways disorder	ADRENOCORTICOTROPIC HORMONE	S				
	UNSPECIFIED INGREDIENT	S				
	CLOBAZAM	C				
	VALPROIC ACID	C				
	ZONISAMIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
24-Aug-2011	8744220	DIRECT	Y	HO		168 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyskinesia	CORTICOTROPIN	S	INTRAMUSCULAR	45 UNITS DAILY		
Bacterial translocation						
Diarrhoea						
Enteritis						
Hypertension						
Hypokalaemia						
Infantile spasms						
Occult blood positive						
Pneumatosis intestinalis						
Pyrexia						
Respiratory tract infection viral						
Sleep disorder						
Viral infection						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Sep-2011	8108297	EXPEDITED (15-DAY)	Y	HO	11-ADE-SU-0076-ACT	66 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypoaesthesia	H.P. ACTHAR	S		80 IU SC DAILY X 5 DAYS		
Vertigo	COPAXONE	C				
Asthenia	AMPYRA	C				
Thrombocytopenia	CADUET	C				
	PROTONIX	C				
	MYSOLINE	C				
	NUVIGIL	C				
	MICARDIS	C				
	NEXIUM	C				
	CALCIUM CARBONATE	C				
	CENTRUM SILVER	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Sep-2011	8165403	EXPEDITED (15-DAY)	N	HO	11-ADE-SU-0092-ACT	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tremor	H.P. ACTHAR	S		80 IU IM DAILY X 5 DAYS		
Dizziness	TYSABRI	C				
Altered state of consciousness	KEPPRA	C				
Loss of consciousness	BACLOFEN	C				
Staphylococcal infection	PROVIGIL	C				
	ZOLOFT	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Nov-2011	8256767	EXPEDITED (15-DAY)	N	OT	US-US-EMD SERONO, INC.-233212J10USA	55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood glucose increased	REBIF	S				
Blood potassium abnormal	ACTHAR GEL-SYNTHETIC	S				
Multiple sclerosis relapse						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Dec-2011	8584446	DIRECT	Y	HO		53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Eyelid oedema	H.P. ACTHAR	S		1 CC @ PER DAY FOR 5 DAYS	1 DAY	
Body temperature decreased						
Face oedema						
Oedema peripheral						
Oropharyngeal pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jan-2012	8329443	DIRECT	Y			48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspnoea	ACTHAR	S	SUBCUTANEOUS	80UNITS DAILY X 5 DAYS SQ		QUESTCOR
Generalised oedema						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jan-2012	8355570	EXPEDITED (15-DAY)	N	HO	DKLU1075795	213 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastrooesophageal reflux disease	SABRIL	S	ORAL	1000 MG MILLIGRAM (S), 2 IN 1 D, ORAL		
	ACTH	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Jan-2012	8391075	EXPEDITED (15-DAY)	N	HO	12-ADE-SU-0004-ACT	213 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	H.P. ACTHAR	S		60-70 IU IM QD - TAPER		
Vomiting	VIGABATRIN	C				
Dehydration						
Gastrooesophageal reflux disease						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Feb-2012	8401643	EXPEDITED (15-DAY)	Y	DE	FR-ASTRAZENECA-2012SE08099	61 YR	Female	FRA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Intestinal infarction	ARIMIDEX	S	ORAL			ZENECA
Hypertension	INEXIUM	S	ORAL			
	AVASTIN	S	INTRAVENOUS			
	RIVOTRIL	S	ORAL			
	ZOMETA	S	INTRAVENOUS			
	NICARDIPINE HYDROCHLORIDE	S	UNKNOWN			
	PRIMPERAN	S	ORAL			
	LYRICA	S	ORAL			
	CORTICOTROPIN	S	UNKNOWN			
	DURAGESIC	C				
	ACETAMINOPHEN	C				
	LOVENOX	C				
	ORAMORPH SR SUSTAINED RELEASE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Feb-2012	8429154	EXPEDITED (15-DAY)	Y	HO	12-ADE-SU-0016-ACT	80 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Acute myocardial infarction	H.P. ACTHAR	S	INTRAMUSCULAR	80 IU IM TWICE A WEEK		
	HYDRALAZINE	C				
	NIACIN	C				
	LIPITOR	C				
	AMLODIPINE	C				
	FUROSEMIDE	C				
	LOSARTAN POTASSIUM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Feb-2012	8661765	EXPEDITED (15-DAY)	N	HO	DKLU1076498	1 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspnoea	SABRIL	S	ORAL	SEE IMAGE		
Viral infection	ONFI	S	ORAL	5 MG MILLIGRAM(S), 1 IN 1 D, ORAL		
Decreased appetite	ACTH	S		0.43 ML MILLILITRE(S), 2 IN 1 D		
Heart rate increased	AMPICILLIN	C				
Dehydration	ZANTAC	C				
Irritability						
Vomiting						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2012	8434121	EXPEDITED (15-DAY)	Y	HO	12-ADE-SU-0019-ACT	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Acute abdomen	H.P. ACTHAR	S		80 IU IM TWICE A WEEK		
Diarrhoea	ROCALTROL	C				
Diverticular perforation	METOLAZONE	C				
Renal failure acute	LASIX	C				
Refusal of treatment by patient	MINOXIDIL	C				
	ZOCOR	C				
	LISINOPRIL	C				
	TUMS	C				
	CITALOPRAM	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2012	8455437	EXPEDITED (15-DAY)	Y	HO	QSC-2012-0006	39 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tremor	H.P. ACTHAR	S	SUBCUTANEOUS	1 ML QD, SUBCUTANEOUS		
Tongue biting	INSULIN NPH (INSULIN ISOPHANE PORCINE)	C				
Faecal incontinence	NEXIUM (ESOMEPRAZOLE MAGNESIUM)	C				
Postictal state	LISINOPRIL (LISINOPRIL)	C				
Sinus tachycardia	SIMVASTATIN	C				
Cardiac failure congestive						
Confusional state						
Diabetic nephropathy						
Fall						
Feeling abnormal						
Grand mal convulsion						
Hyperglycaemia						
Hypertensive emergency						
Mitral valve incompetence						
Proteinuria						
Pulmonary valve incompetence						
Renal failure acute						
Tricuspid valve incompetence						
Urinary incontinence						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Mar-2012	8468093	EXPEDITED (15-DAY)	N	HO	QSC-2012-0011	58 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dysarthria	H.P. ACTHAR	S		UNK		
Condition aggravated						
Fall						
Gait disturbance						
Multiple sclerosis						
Paralysis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Mar-2012	8495162	EXPEDITED (15-DAY)	Y	HO	QSC-2012-0018	334 DAY	Male	ITA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diabetes mellitus	H.P. ACTHAR	S	INTRAMUSCULAR	20 IU/DIE, QD, INTRAMUSCULAR ; 20, QOD, INTRAMUSCULAR ; 20 IU, BIW, INTRAMUSCULAR	7 DAY	
Enteritis	VALPROATE SODIUM	C				
Adrenal disorder						
Alkalosis hypokalaemic						
Blood cortisol increased						
Bronchopneumonia						
Convulsion						
Cushingoid						
Dehydration						
Electrolyte imbalance						
Hirsutism						
Hyperadrenocorticism						
Hypernatraemia						
Lymphopenia						
Thrombocytopenia						
Weight increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Mar-2012	8486002	EXPEDITED (15-DAY)	N	OT	PHEH2012US006819		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fluid retention	GILENYA	S		UNK		NOVARTIS
	H.P. ACTHAR	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Apr-2012	8491940	EXPEDITED (15-DAY)	Y	OT	PHHY2012IT027874		Male	ITA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Growth retardation	CICLOSPORIN	S		4-5 mg/kg, UNK		NOVARTIS
Cushingoid	CICLOSPORIN	S		2 mg/kg, UNK		NOVARTIS
Posterior reversible encephalopathy syndrome	PREDNISONE	S				
Hypertension	METHYLPREDNISOLONE	S	INTRAVENOUS	20 mg/kg, for three to five times		
	TACROLIMUS	S		0.1 mg/kg, UNK		
	TACROLIMUS	S		0.018 mg/kg, UNK		
	RITUXIMAB	S		375 mg/m2, UNK		
	CORTICOTROPIN	S	INTRAMUSCULAR	1 mg/week		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Apr-2012	8491941	EXPEDITED (15-DAY)	Y	OT	PHHY2012IT027892		Male	ITA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cushingoid	CICLOSPORIN	S		4-5 mg/kg, UNK		NOVARTIS
Glomerular filtration rate decreased	CICLOSPORIN	S		2 mg/kg, UNK		NOVARTIS
	PREDNISONE	S				
	METHYLPREDNISOLONE	S	INTRAVENOUS	20 mg/kg, for three to five times		
	MYCOPHENOLATE MOFETIL	S		20-30 mg/kg, UNK		
	CYCLOPHOSPHAMIDE	S		2.5 mg/kg, for 8 weeks		
	CORTICOTROPIN	S	INTRAMUSCULAR	1 mg/week		
	PLASMAPHERESIS BLOOD PACK UNIT	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Apr-2012	8532242	DIRECT	Y	OT		40 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dysarthria	ACTHAR	S	SUBCUTANEOUS	80UN BIW SQ		QUESTCOR
Muscle spasms	MICARDIS	S				
	RENVELA	S				
	PRILOSEC	C				
	AMLODIPINE	C				
	CITALOPRAM	C				
	SIMVASTATIN	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-May-2012	8584524	DIRECT	Y				Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	H.P. ACTHAR	S				QUESTCOR

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-May-2012	8568167	DIRECT		OT		42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Oedema peripheral	H.P. ACTHAR	S		INJECTABLE QD		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-May-2012	7233393	EXPEDITED (15-DAY)	Y	DE,HO,OT	US-ROCHE-676835		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Aplastic anaemia	MABTHERA	S	INTRAVENOUS DRIP	750 MG/M2, Q2W		
Sepsis	ACTH	S	INTRAMUSCULAR	25 IU/M2, QOD		
	HUMAN IMMUNOGLOBULIN G	C		UNK		
	CLONIDINE	C		0.5 MG, TID		
	AMLODIPINE	C		3 MG, BID		
	CALCIUM CARBONATE	C		750 MG, BID		
	CAPTOPRIL	C		6.5 MG, BID		
	CAPTOPRIL	C		10 MG, QHS		
	NIFEDIPINE	C		3.5 MG, PRN		
	BACTRIM	C				
	PENTAMIDINE	C		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-May-2012	8582605	EXPEDITED (15-DAY)	Y	OT	PHHY2012JP045341	80 YR	Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vein disorder	EXJADE	S	ORAL	125 mg, daily		NOVARTIS
Oedema peripheral	CORTICOTROPIN	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-May-2012	8600032	DIRECT	Y	HO		65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure decreased	ACTHAR	S	SUBCUTANEOUS	80 UNITS DAILY SUBCUTANOUS		QUESTCOR
Heart rate decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2012	9182131	NON-EXPEDITED	Y	HO,LT,RI	QSC-2011-0093	3 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Bacterial sepsis	H.P. ACTHAR	S	INTRAMUSCULAR			QUESTCOR

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2012	9182139	NON-EXPEDITED	Y	HO,LT,RI	QSC-2011-0094	213 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Bacterial sepsis	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	INTRAMUSCULAR			QUESTCOR

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2012	9182147	NON-EXPEDITED	Y	HO,RI	QSC-2011-0095	182 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pneumocystis jirovecii pneumonia	ACTHAR	S	INTRAMUSCULAR	75 iu/m2	42 DAY	QUESTCOR

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2012	9182156	NON-EXPEDITED	Y	HO	QSC-2011-0111	1 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Infection	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	INTRAMUSCULAR	BID with taper		QUESTCOR

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2012	9182170	NON-EXPEDITED	Y	OT	QSC-2011-0142	44 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood glucose increased	H.P. ACTHAR GEL	S		2x		QUESTCOR
Polyuria	TOPMAX (TOPIRAMATE)	C				
Feeling abnormal	AMITRIPTYLINE (AMITRIPTYLINE)	C				
	AMBIEN (ZOLPIDEM TARTRATE)	C				
	GABAPENTIN (GABAPENTIN)	C				
	TEGRETOL (CARBAMAZEPINE)	C				
	UNKNOWN					
Dehydration						
Thirst						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2012	9182181	NON-EXPEDITED		HO	QSC-2012-0028	304 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diarrhoea	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	INTRAMUSCULAR			QUESTCOR
Convulsion						
Cushingoid						
Flatulence						
Oral candidiasis						
Retching						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2012	9182188	NON-EXPEDITED	Y	HO	QSC-2012-0069	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood potassium decreased	H.P. ACTHAR GEL	S	SUBCUTANEOUS			QUESTCOR
	CLONAZEPAM (CLONAZEPAM) (CLONAZEPAM)	C				
	LEXAPRO (ESCITALOPRAM HORMONE)	C				
	VITAMIN D (ERGOCALCIFEROL)	C				
	LEVOTHYROXINE (LEVOTHYROXINE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jun-2012	9182193	NON-EXPEDITED		HO,LT	QSC-2012-0078	304 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pneumonia	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	SUBCUTANEOUS			QUESTCOR

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Jun-2012	8665706	EXPEDITED (15-DAY)	Y	HO	QSC-2012-0102	48 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Leukocytosis	H.P. ACTHAR	S		UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Jul-2012	8648320	EXPEDITED (15-DAY)	Y	OT	NL-ROXANE LABORATORIES, INC.-2012-RO-01501RO	1 YR	Male	NLD

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dehydration	FUROSEMIDE	S				ROXANE
Renal failure chronic	FUROSEMIDE	S	INTRAVENOUS			ROXANE
Renin decreased	AMLODIPINE	S				ROXANE
Drug ineffective	SODIUM POLYSTYRENE SULFONATE	S	ORAL			ROXANE
	HYDROCHLOROTHIAZIDE	S				
	HYDROCHLOROTHIAZIDE	S	ORAL			
	ATENOLOL	S				
	ACTH	S				
	MISOPROSTOL	S	ORAL	400 mg		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Jul-2012	8675279	DIRECT	Y	HO		73 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	ACTHAR	S		ACTHAR 80 UNITS TWICE A WEEK X 6MO 057 SUB Q		QUESTCOR
Hypertension	AMLODIPINE	C				
	ATENOLOL	C				
	CALCIUM	C				
	FUROSEMIDE	C				
	LOVAZA	C				
	POTASSIUM	C				
	PRILOSEC	C				
	SPIRONOLACTONE	C				
	TRAMADOL HYDROCHLORIDE	C				
	VITAMIN D	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Jul-2012	8677966	DIRECT	Y	OT		59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Feeling cold	ACTHAR	S	SUBCUTANEOUS	40U TWICE WEEKLY		
Dizziness						
Joint swelling						
Nausea						
Oedema peripheral						
Pruritus generalised						
Vomiting						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Jul-2012	8672432	EXPEDITED (15-DAY)	Y	OT	QSC-2012-0116	43 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Stevens-Johnson syndrome	H.P. ACTHAR	S	SUBCUTANEOUS	80 UNITS, QD, SUBCUTANEOUS		
Erythema multiforme	AMOXICILLIN	C				
Drug hypersensitivity	VIT D (ERGOCALCIFEROL)	C				
	FOLIC ACID	C				
	HYDROCHLOROTHIAZIDE	C				
	LORATIDINE	C				
	VIT C (ASCORBIC ACID)	C				
	LEXAPRO	C				
	CRANBERRY (VACCINIUM MACROCARPON)	C				
	BISACODYL (BISACODYL)	C				
	PROVIGIL	C				
	BACLOFEN	C				
	GABAPENTIN (GABAPENTIN)	C				
	COUMADIN	C				
	DONEPEZIL HYDROCHLORIDE	C				
	TEMAZEPAM	C				
	LOPERAMIDE HYDROCHLORIDE	C				
	NYSTOP (NYSTATIN)	C				
	HYDROCODONE BITARTRATE & ACETAMINOPHEN	C				
	PROMETHAZINE	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Jul-2012	8698231	EXPEDITED (15-DAY)	Y	DS,OT	QSC-2012-0128	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Obliterative bronchiolitis	ACTHAR	S		0/8 ML THREE TIMES PER WEEK ; 0.8 ML, IW		
	CELLCEPT	S				
	ASPIRIN (CHILDREN (ACETYLSALICYLIC ACID)	C				
	BENICAR	C				
	FUROSEMIDE (FUROSEMIDE)	C				
	METOLAZONE	C				
	POTASSIUM CHLORIDE	C				
	VITAMIN D 2000 (CALCIUM CARBONATE, COLECALCIFEROL)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jul-2012	8715173	EXPEDITED (15-DAY)	Y	DE	FK201201939	213 DAY	Female	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Herpes zoster	ACYCLOVIR SODIUM	S		INTRAVENOUS (NOT OTHERWISE SPECIFIED)		
Multi-organ failure	CORTICOTROPIN	S		0.005 MG/KG, ONCE EVERY MORNING		
Disseminated intravascular coagulation	HUMAN IMMUNOGLOBULIN G	S		INTRAVENOUS (NOT OTHERWISE SPECIFIED)		
General physical health deterioration	VALPROATE SODIUM	C				
Shock haemorrhagic	ZONISAMIDE	C				
Ascites						
Brain oedema						
Capillary leak syndrome						
Cardiovascular insufficiency						
Haemorrhage intracranial						
Hepatic failure						
Pleural effusion						
Rash						
Respiratory distress						
Respiratory failure						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jul-2012	8710547	DIRECT	Y	OT		65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Skin irritation	ACTHAR	S	INTRAMUSCULAR	1 ML (80 UNITS DAILY) IM		QUESTCOR
Abdominal distension						
Drug ineffective						
Hallucination						
Palpitations						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Aug-2012	8734893	EXPEDITED (15-DAY)	Y	DE	QSC-2012-0141	71 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Acute coronary syndrome	ADRENOCORTICOTROPIC HORMONE	S	SUBCUTANEOUS	80 UNITS, BIW, SUBCUTANEOUS		
Sudden death	CELLCEPT	C				
	UNSPECIFIED INGREDIENTS	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Aug-2012	8758199	EXPEDITED (15-DAY)	Y	OT	QSC-2012-0162		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Anaemia	ADRENOCORTICOTROPIC HORMONE	S	INTRAMUSCULAR		7 DAY	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Aug-2012	8725672	EXPEDITED (15-DAY)	Y	OT	US-ABBOTT-12P-163-0962530-00	30 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Thrombocytopenia	VALPROATE SODIUM	S				
Status epilepticus	PHENOBARBITAL	S				
Drug effect decreased	PENTOBARBITAL SODIUM	S		4-5 mg/kg/hr		
Rash	FOSPHENYTOIN	S				
	MIDAZOLAM	S		Continuous drip		
	PROPOFOL	S		Drip		
	TOPIRAMATE	S		Max dose 400 mg daily		
	LEVETIRACETAM	S		Max 2500 mg twice daily		
	OXCARBAZEPINE	S		Max 1200 mg twice daily		
	NEURONTIN	S		Max 1200 mg three times daily		
	HUMAN IMMUNOGLOBULIN G	S		0.4 mg/kg/day	5 DAY	
	ACETAZOLAMIDE	S		Max 500 mg twice daily		
	CORTICOTROPIN	S			2 WEEK	
	ACYCLOVIR	C				
	VANCOMYCIN	C				
	CEFTRIAXONE	C				
	BENZODIAZEPINE RELATED DRUGS	C				
	MAGNESIUM	C				
	KETAMINE HYDROCHLORIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Aug-2012	8742728	EXPEDITED (15-DAY)	Y	OT	DKLU1083632		Male	JPN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Convulsion	ONFI	S				
Drug ineffective	VALPROIC ACID	S				
Drop attacks	TOPIRAMATE	S				
Fall	CLONAZEPAM	S				
Head injury	PHENYTOIN	S				
Developmental delay	LAMOTRIGINE (LAMOTRIGINE)	S				
	GABAPENTIN (GABAPENTIN)	S				
	CARBAMAZEPINE	S				
	PHENOBARBITAL	S				
	CORTICOTROPIN (CORTICOTROPIN)	S				
	ZONISAMIDE	C				
	SULTIAME (SULTIAME)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Oct-2012	8817060	DIRECT	Y	OT		45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Swelling	ACTHAR	S	SUBCUTANEOUS	80 units, subq		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	8758203	EXPEDITED (15-DAY)	Y	DE,HO	QSC-2012-0164	8 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Syncope	ADRENOCORTICOTROPIC HORMONE	S	INTRAMUSCULAR		7 DAY	
Sudden death	KLONOPIN (CLONAZEPAM) (TABLETS)	S				
Anger	TOPAMAX (TOPIRAMATE)	S				
	GEODON	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Oct-2012	8844620	EXPEDITED (15-DAY)	Y	HO,OT	QSC-2012-0160	4 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Neutropenia	ADRENOCORTICOTROPIC HORMONE	S	INTRAMUSCULAR	14 IU, qod, Intramuscular		
	BACTRIM	C				
	ZANTAC (RANITIDINE HYDROCHLORIDE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Oct-2012	8855903	DIRECT	Y				Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Exostosis	ACTHAR	S	SUBCUTANEOUS		5 DAY	
Arthritis						
Hyperglycaemia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Nov-2012	8909726	EXPEDITED (15-DAY)	Y	DE	QSC-2012-0288	57 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myocardial infarction	H.P. ACTHAR	S	SUBCUTANEOUS	UNK, biw, Subcutaneous		
Cardiac arrest						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Nov-2012	8909731	EXPEDITED (15-DAY)	Y	HO	QSC-2012-0285		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Adrenal disorder	H.P. ACTHAR	S		UNK		
Blood electrolytes decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Nov-2012	8816526	EXPEDITED (15-DAY)	Y	DE,HO,OT	QSC-2012-0203	70 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Respiratory failure	ADRENOCORTICOTROPHIC HORMONE	S	INTRAMUSCULAR			
Inappropriate antidiuretic hormone secretion	LOSARTAN (LOSARTAN)	C				
Oesophagitis	SPIRONOLACTONE (SPIRONOLACTONE)	C				
Gastrointestinal haemorrhage	LASIX (FUROSEMIDE)	C				
	KEPPRA (LEVETIRACETAM)	C				
	PLAVIX (CLOPIDOGREL BISULFATE)	C				
Oxygen saturation decreased	AMLODIPINE (AMLODIPINE)	C				
Hypophagia	LABETALOL (LABTALOL)	C				
Pneumonia aspiration	ALPRAZOLAM (ALPRAZOLAM)	C				
	LEVOTHYROXINE (LEVOTHYROXINE)	C				
	CRSETOR (ROSUVASTATIN CALCIUM)	C				
	OMEPRAZOLE (OMEPRAZOLE)	C				
	ACETAMINOPHEN (PARACETAMOL)	C				
	OXYCODONE (OXYCODONE)	C				
	ASPIRIN (ACETYLSALICYCLIC AICD)	C				
	SALT (SODIUM CHLORIDE)	C				
	MAGNESIUM OXIDE (MAGNESIUM OXIDE)	C				
	VITAMIN D NOS (VITAMIN D NOS)	C				
	CALCIUM CITRATE (CALCIUM CITRATE)	C				
Abscess intestinal						
Diverticular perforation						
General physical health deterioration						
Hyponatraemia						
Hypotension						

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pallor						
Pneumonia aspiration						
Pulmonary embolism						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Nov-2012	8913498	EXPEDITED (15-DAY)		OT	QSC-2012-0281	75 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pneumothorax	ACTHAR	S				
Anxiety						
Asthenia						
Cough						
Dyspepsia						
Faecal incontinence						
Fall						
Fatigue						
Fluid retention						
Gait disturbance						
Gastrointestinal motility disorder						
Hypophagia						
Joint stiffness						
Joint swelling						
Local swelling						
Nausea						
Rib fracture						
Sleep disorder						
Syncope						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Dec-2012	8984049	EXPEDITED (15-DAY)	Y	DE,HO	OSC-2012-0336	64 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cerebrovascular accident	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S				
	TYSABRI	C				
	ADDERALL (AMFETAMINE ASPARTATE, AMFETAMINE SULFATE, DEXAMFETAMINE SACCHARATE, DEXAMFETAMINE SULFATE)	C				
	AMBIEN (ZOLPIDEM TARTRATE)	C				
	FIORICET (BUTALBITAL, CAFFEINE, PARACETAMOL)	C				
	FLEXERIL (CYCLOBENZAPRINE HYDROCHLORIDE)	C				
	LANTUS (INSULIN GLARGINE)	C				
	LASIX (FUROSEMIDE)	C				
	CYMBALTA (DULOXETINE HYDROCHLORIDE)	C				
	DETROL LA (TOLTERODINE L-TARTRATE)	C				
	PEPCID (FAMOTIDINE)	C				
	LIPITOR (ATORVASTATIN CALCIUM)	C				
	LISINOPRIL (LISINOPRIL)	C				
Malaise						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8974776	DIRECT	Y	OT		32 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Acne	ACTHAR	S	SUBCUTANEOUS	40 units Monday and Friday SQ		QUESTCOR
Weight increased	VIT D	C				
	ENALAPRIL	C				
Headache						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Dec-2012	8978901	DIRECT		HO		63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood pressure increased	ACTHAR	S		80 unites injection		
	ACTHAR	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Dec-2012	9006160	EXPEDITED (15-DAY)	Y	DE	QSC-2012-0361	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Proteinuria	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S		80 units, unk, unknown		
	HYDRALAZINE	C				
	LANTUS (INSULIN GLARGINE)	C				
	PREDNISONE	C				
	ALDACTONE (SPIRONOLACTONE)	C				
	FUROSEMIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2013	9034030	DIRECT	Y	HO		30 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Palpitations	H.P. ACTHAR	S	INTRAMUSCULAR	80 U IM QD		QUESTCOR
Arrhythmia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Jan-2013	9006156	EXPEDITED (15-DAY)	Y	HO	QSC-2012-0299	34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cardiomyopathy	ACTHAR GEL-SYNTHETIC	S	SUBCUTANEOUS	40 units		
Influenza like illness	PREDNISONE (PREDNISONE)	C				
	AZITHROMYCIN (AZITHROMYCIN)	C				
	CELEXA (CITALOPRAM HYDROBROMIDE)	C				
	FUROSEMIDE (FUROSEMIDE)	C				
	LABETALOL (LAETALOL)	C				
	LOSARTAN (LOSARTAN)	C				
	VITAMIN D (COLECALCIFEROL)	C				
Hypersensitivity						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Jan-2013	8960572	EXPEDITED (15-DAY)	Y	OT	DKLU1086655	213 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Haematochezia	SABRIL	S	ORAL			
	CLONAZEPAM (CLONAZEPAM) (CLONAZEPAM)	C				
	ZONEGRAN (ZONISAMIDE)	C				
	PEPCID (FAMOTIDINE)	C				
	POLYETHYLENE GLYCOL (MACROGOL)	C				
Constipation						
Eye movement disorder						
Hemiparesis						
Movement disorder						
Seizure cluster						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2013	8967662	EXPEDITED (15-DAY)	Y	HO	QSC-2012-0326	2 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	INTRAMUSCULAR	40 units, bid, Intramuscular		
Dilatation intrahepatic duct congenital	IMMUNOGLOBULIN (IMMUNOGLOBULINS NOS)	C				
Anaemia						
Hypoalbuminaemia						
Hyponatraemia						
Oesophageal varices haemorrhage						
Pleural effusion						
Sinus bradycardia						
Upper gastrointestinal haemorrhage						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Feb-2013	9094388	DIRECT	Y				Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Influenza	ACTHAR	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Feb-2013	9146647	EXPEDITED (15-DAY)	Y	DE,HO	QSC-2013-0021		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	SUBCUTANEOUS	80 units, biw, Subcutaneous 01/--/2013 to UNK		
Lung infection						
Pneumonia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2013	9093460	DIRECT	Y				Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Flushing	ACTHAR	S	SUBCUTANEOUS			QUESTCOR
Local swelling						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2013	9146182	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0029	70 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pulmonary oedema	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	SUBCUTANEOUS	80 units, biw, Subcutaneous		
	ALLOPURINOL	C				
	ASPIRIN (ACETYLSALICYLIC ACID)	C				
	ATORVASTATIN (ATORVASTATIN)	C				
	AVAPRO (IRBESARTAN)	C				
	COLCHICINE (COLCHICINE)	C				
	DEPAKOTE (VALPROATE SEMISODIUM)	C				
	LABETALOL (LABETALOL)	C				
	MINOXIDIL (MINOXIDIL)	C				
	NORVASC (AMLODIPINE BESILATE)	C				
	TRIAMTERENE AND HYDROCHLOROTHIAZIDE (HYDROCHLOROTHIAZIDE, TRIAMTERENE)	C				
	VITAMIN D3 (COLECALCIFEROL)	C				
	CENTRUM (MINERAL NOS, VITAMINS NOS)	C				
Hypertension						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2013	9154692	EXPEDITED (15-DAY)		HO	QSC-2013-0015	46 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pneumothorax	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	SUBCUTANEOUS			
Pneumothorax	LASIX (FUROSEMDIE)	C				
Bacterial infection	SPIRONOLACTONE (SPIRONOLACTONE)	C				
Urinary retention	BACTRIM	C				
	OXYCODONE (OXYCODONE)	C				
	WARFARIN (WARFARIN)	C				
	TAMSULOSIN (TAMSULOSIN)	C				
	COZAAR (LOSARTAN POTASSIUM)	C				
Atrial fibrillation						
Empyema						
Infection						
Nephrotic syndrome						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Mar-2013	9149444	DIRECT		OT			Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Injection site discolouration	ACTHAR	S	SUBCUTANEOUS	1 ML 2 injections week1 sq	6 MTH	
Asthenia						
Blood creatinine increased						
Blood pressure fluctuation						
Capillary fragility						
Injection site reaction						
Mood swings						
Pulse abnormal						
Sleep disorder						
Tremor						
Weight decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Mar-2013	9146168	EXPEDITED (15-DAY)	Y	DE	QSC-2013-0036	64 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Acute pulmonary oedema	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	INTRAMUSCULAR			
Cardiac failure						
Respiratory failure						
Sudden death						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Mar-2013	9169062	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0054	10 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Subclavian vein thrombosis	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S		80 units		
Coagulation time prolonged	LISINOPRIL (LISINOPRIL DIHYDRATE) (UNKNOWN	C				
	LOSARTAN (LOSARTAN POTASSIUM)	C				
	SYMBICORT	C				
	CETIRIZINE (CETIRIZINE)	C				
	ERGOCALCIFEROL (ERGOCALCIFEROL)	C				
	LASIX (FUROSEMIDE)	C				
Jugular vein thrombosis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Mar-2013	9167978	EXPEDITED (15-DAY)	Y	DS,OT	2013034874	25 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Asthenia	INTRAVENOUS IMMUNOGLOBULIN (IVIG) (IMMUNE GLOBULIN INTRAVENOUS (HUMAN) 10% LIQUID)	S				
	MYCOPHENOLATE MOFETIL (MYCOPHENOLATE MOFETIL)	S				
	METHYLPREDNISOLONE (METHYLPREDNISOLONE)	S				
	TACROLIMUS (TACROLIMUS)	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Mar-2013	9168007	EXPEDITED (15-DAY)	Y	DS,OT	2013034804	25 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Walking aid user	METHYLPREDNISOLONE (METHYLPREDNISOLONE)	S			8 WEEK	
No therapeutic response	TACROLIMUS (TACROLIMUS)	S				
Condition aggravated						
Dermatomyositis						
Muscle atrophy						
Muscular weakness						
Off label use						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Mar-2013	9168038	EXPEDITED (15-DAY)	Y	OT	2013034867	45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Muscular weakness	INTRAVENOUS IMMUNOGLOBULIN	S				
Rash	AZATHIOPRINE	S				
Nail disorder	RITUXIMAB (RITUXIMAB)	S				
Drug ineffective for unapproved indication	CYCLOSPORINE (CICLOSPORIN)	S				
Headache	METHOTREXATE (METHOTREXATE)	S				
Chills	PREDNISONE (PREDNISONE)	S				
Nausea	HP ACTHAR (CORTICOTROPIN)	S				
Condition aggravated						
Dermatomyositis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2013	9167448	DIRECT	Y	HO		21 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Proteinuria	ACTHAR HP	S		80u/1ml 5 ml vial		QUESTCOR
No therapeutic response						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Mar-2013	9168636	DIRECT	Y	HO,LT		37 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Vision blurred	ACTHAR GEL-SYNTHETIC	S	SUBCUTANEOUS			QUESTCOR
Blood potassium decreased						
Heart rate decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Apr-2013	9263568	DIRECT	Y	OT		29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tremor	ACTHAR	S	SUBCUTANEOUS	1 ml biw subcutaneous		
Feeling jittery	PREDNISONE	C				
Palpitations						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
29-Apr-2013	9264760	DIRECT	Y			36 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Alopecia	ACTHAR	S	SUBCUTANEOUS	80 units		QUESTCOR

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-May-2013	9217386	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0088	74 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myopathy	H.P. ACTHAR GEL	S	SUBCUTANEOUS	80 UNITS, BIW, SUBCUTANEOUS		
Asthenia	BUMEX (BUMETANIDE)	C				
	POTASSIUM CHLORIDE (POTASSIUM CHLORIDE)	C				
	VITAMIN D (ERGOCALCIFEROL)	C				
	ASPIRIN LOW (ACETYLSALICYLIC ACID)	C				
	COREG (CARVEDILOL)	C				
	CALCITRIOL (CALCITRIOL)	C				
	FISH OIL (FISH OIL)	C				
	ALDACTONE (SPIRONOLACTONE)	C				
	DILTIAZEM	C				
	FLOMAX (MORNIFLUMATE)	C				
	HYDRALAZINE (HYDRALAZINE)	C				
	MAGNESIUM (MAGNESIUM SULFATE)	C				
Blood glucose increased						
Deep vein thrombosis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-May-2013	9277342	DIRECT	Y	OT		1 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Muscle spasms	ACTHAR	S		0.4 cc bid x 7 d, o 18 cc .. c 6 d		
Disease recurrence						
Drug ineffective						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-May-2013	9302647	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0131	273 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ventricular extrasystoles	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S		75 units/m2, for 2 wks		
Hypertension						
Ventricular tachycardia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-May-2013	9302656	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0128	59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Atrial fibrillation	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	SUBCUTANEOUS	80 units		
Coronary artery embolism	COPAXONE (GLATIRAMER ACETATE)	C				
Eye haemorrhage	DOXEPIN	C				
Snoring	OMEPRAZOLE	C				
Erythema	ESTROGEN (ESTRADIOL)	C				
	LISINOPRIL	C				
	METOPROLOL	C				
	RANITIDINE (RANITIDINE)	C				
	SIMVASTATIN	C				
	WARFARIN	C				
	PROGRAF (TACROLIMUS)	C				
	PREDNISONE	C				
Amaurosis fugax						
Dyspnoea exertional						
Infusion site infection						
Palpitations						
Sleep apnoea syndrome						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-May-2013	9302068	EXPEDITED (15-DAY)		OT	US-BAXTER-2013BAX016834	46 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hyponatraemia	5% DEXTROSE INJECTION USP	S	UNKNOWN			BAXTER
	5% DEXTROSE INJECTION USP	S				BAXTER
	ACTH	S				
	DEXAMETHASONE	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Jun-2013	9331876	EXPEDITED (15-DAY)	Y	HO	ACO_35816_2013	47 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fall	AMPYRA	S	ORAL			
Constipation	TESTOSTERONE (TESTOSTERONE PROPIONATE)	C				
Drug dose omission	OXYCODONE HCL (OXYCODONE HYDROCHLORIDE)	C				
Blood potassium decreased	OXYCONTIN (OXYCODONE HYDROCHLORIDE)	C				
	XANAX (ALPRAZOLAM)	C				
	ADDERALL (AMFETAMINE ASPARTATE, AMFETAMINE SULFATE, DEXAMFETAMINE SACCHARATE, DEXAMFETAMINE SULFATE)	C				
	CLARITIN (LORATADINE)	C				
	PRENATAL (ASCORBIC ACID, CALCIUM PANTOTHENATE, CYANOCOBALAMIN, ERGOCALCIFEROL, NICOTINAMIDE, PYRIDOXINE HYDROCHLORIDE, RETINOL PALMITATE, RIBOFLAVIN, THIAMINE MONONITRATE)	C				
	COSAMIN (CHONDROITIN SULFATE, GLUCOSAMINE HYDROCHLORIDE, MANGANESE ASCORBATE)	C				
	ZOFRAN (ONDANSETRON HYDROCHLORIDE)	C				
	ABILIFY (ARIPIPRAZOLE)	C				
	SOMA CMPD (ACETYLSALICYLIC ACID, CARISOPRODOL)	C				
Balance disorder						
Insomnia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Jun-2013	9341353	DIRECT	Y	OT		69 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspnoea	ACTHAR	S		80u/ml Injectable 1 tiw		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jun-2013	9350575	DIRECT	Y	HO		60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Migraine	ACTHAR GEL-SYNTHETIC	S	SUBCUTANEOUS	40 U QD SUBCUTANEOUS		QUESTCOR
Muscular weakness	CLONAZEPAM	C				
	VALIUM	C				
	CYMBALTA	C				
	ZOFRAN	C				
	TORADOL	C				
	DHE	C				
	PHENERGAN	C				
	BENEDRYL	C				
Dyskinesia						
Psychogenic seizure						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Jun-2013	9375492	EXPEDITED (15-DAY)			ES-EISAI INC-E2090-02715-SPO-ES	9 DAY	Male	ESP

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	ZONISAMIDE	S		UNKNOWN		
	PHENOBARBITAL	S		UNKNOWN		
	LEVETIRACETAM	S		UNKNOWN		
	CLONAZEPAM	S		UNKNOWN		
	VIGABATRIN	S		UNKNOWN		
	ACTH	S		UNKNOWN		

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Jul-2013	9317308	EXPEDITED (15-DAY)	Y	DE,HO	QSC-2013-0140	72 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pancytopenia	ADRENOCORTICOTROPIC HORMONE	S	SUBCUTANEOUS	80 units, bid, Subcutaneous		
Acute respiratory failure	FUROSEMIDE (FUROSEMIDE)	C				
Oedema peripheral	CARVEDILOL (CARVEDILOL)	C				
Oedema	ISISORBIDE DINITRATE (ISISORBIDE DINITRATE)	C				
Sepsis	VITAMIN D NOS (VITAMIN D NOS)	C				
	TYLENOL WITH CODEIN #3 (CAFFEINE, CODEINE PHOSPHATE, PARACETAMOL)	C				
	FISH OIL (FISH OIL)	C				
	FENOFIBRATE 9FENOFIBRATE)	C				
	ALLOPURINOL	C				
	THYROID (THYROID)	C				
Defaecation urgency						
Heart rate irregular						
Lower gastrointestinal haemorrhage						
Peritonitis						

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Jul-2013	9278845	NON-EXPEDITED			US-PFIZER INC-2013141522	42 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	Neurontin	S		UNK		PFIZER
Urticaria	AMOXICILLIN	S		UNK		PFIZER
	ERYTHROMYCIN	S		UNK		
	AMOXIL	S		UNK		
	MOTRIN	S		UNK		
	ATCH	S		UNK		
	KEFLEX	S		UNK		

FDA Adverse Event Reporting System (FAERS)
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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Jul-2013	9364414	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0116	41 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Colitis ischaemic	H.P. ACTHAR GEL	S				
Enterocolitis infectious	LISINOPRIL (LISINOPRIL)	C				
Rectal haemorrhage	AMLODIPINE (AMLODIPINE)	C				
Hypernatraemia	CALCIUM ACETATE (CALCIUM ACETATE)	C				
Hypokalaemia	CLONIDINE (CLONIDINE)	C				
Hypoalbuminaemia	HYDRALAZINE (HYDRALAZINE)	C				
Anxiety	LACTULOSE (LACTULOSE)	C				
Blood pressure increased	METOPROLOL (METOPROLOL)	C				
Local swelling	FISH OIL (FISH OIL)	C				
Asthenia	PANTOPRAZOLE (PANTOPRAZOLE)	C				
Abdominal pain						
Anaemia						
Diverticulitis						
Hypomagnesaemia						
Iron deficiency anaemia						
Malaise						
Renal failure acute						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Jul-2013	9355528	EXPEDITED (15-DAY)		HO,OT	US-SANOFI-AVENTIS-2013SA060829	47 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Multiple sclerosis relapse	AUBAGIO	S	ORAL			
Blood potassium abnormal	CORTICOTROPIN	S				
Fall	AMINOPYRIDINE, 2-	S	ORAL			
Insomnia	AMINOPYRIDINE, 2-	S	ORAL			
Asthenia	TESTOSTERONE	C				
Balance disorder	OXYCODONE HYDROCHLORIDE	C				
Constipation	OXYCONTIN	C				
Transient ischaemic attack	XANAX	C				
	ADDERALL	C				
	CLARITIN	C				
	PRENATAL	C				
	COSAMIN	C				
	ZOFRAN	C				
	ABILIFY	C				
	ACETYLSALICYLIC ACID/ CARISOPRODOL	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jul-2013	9416928	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0222	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Coronary artery disease	H.P. ACTHAR GEL	S				
Fatigue	HYDROCORTISONE (HYDROCORTISONE)	C				
Hypertension						
Pain in extremity						
Pain in jaw						
Tachycardia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Jul-2013	9416932	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0219	41 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cardiomyopathy	H.P. ACTHAR GEL	S		80 units, biw		
Mitral valve incompetence	NORTRIPTYLINE (NORTRIPTYLINE)	C				
Pulmonary hypertension	OMEPRAZOLE (OMEPRAZOLE)	C				
Atelectasis	SINGULAIR	C				
Dyspnoea	NASONEX (MOMETASONE FUROATE)	C				
Carditis	MOBIC (MELOXICAM)	C				
Headache	ALBUTEROL (SALBUTAMOL)	C				
Leukocytosis	MULTIVITAMIN (VITAMINS NOS)	C				
Anxiety						
Aortic valve incompetence						
Cardiac failure congestive						
Hypertension						
Off label use						
Pleural effusion						
Sinus tachycardia						
Systolic dysfunction						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Jul-2013	9422408	DIRECT	Y	OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Swelling face	ACTHAR	S	SUBCUTANEOUS	daily for 5 days		QUESTCOR

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Aug-2013	9447412	EXPEDITED (15-DAY)	Y	HO,OT	QSC-2013-0235	70 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Adenocarcinoma pancreas	H. P. ACTHAR GEL	S	SUBCUTANEOUS	DOSAGE ADMINISTERED EVERY TWO WEEKS FOR SIX MONTHS.		
Dysgeusia						
Fatigue						
Hypoaesthesia						
Hypoaesthesia oral						
Somnolence						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
08-Aug-2013	9454717	EXPEDITED (15-DAY)	Y	DE,HO	QSC-2013-0245	65 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Septic shock	H.P. ACTHAR GEL	S	SUBCUTANEOUS	80 units		
Skin mass	ALLOPURINOL	C				
Haemoglobin decreased	BYSTOLIC	C				
Immunosuppression	CALCITRIOL	C				
Blood glucose increased	CALCIUM CARBONATE W/ VITAMIN D NOS	C				
Blood potassium decreased	DOXAZOSIN	C				
	OMEPRAZOLE	C				
	PROCRIT	C				
	SPIRONOLACTONE	C				
	SYNTHROID	C				
Blood chloride decreased						
Blood creatinine increased						
Haematocrit decreased						
Hypotension						
Impaired healing						
Local swelling						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Aug-2013	9468659	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0257		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Atrial fibrillation	H.P. ACTHAL GEL	S	SUBCUTANEOUS	80 UNITS, BID, SUBCUTANEOUS		
Heart rate increased	ULTRAM	C				
	TUMS (CALCIUM CARBONATE)	C				
	NORVASC (AMLODIPINE BESILATE)	C				
	CRESTOR	C				
	COLCRYS (COLCHICINE)	C				
	CALCITROL (CALCITRIOL)	C				
	ALLOPURINOL	C				
Chest pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Sep-2013	9496404	EXPEDITED (15-DAY)		OT	VE-JNJFOC-20130815817		Male	VEN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Encephalopathy	TOPIRAMATE	S	ORAL			
Multiple-drug resistance	VALPROIC ACID	S	UNKNOWN			
Off label use	NITRAZEPAM	S	UNKNOWN			
	LEVETIRACETAM	S	UNKNOWN			
	ACTH	S	UNKNOWN			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Sep-2013	9499889	DIRECT	Y	OT		55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tremor	ACTHAR	S	INTRAMUSCULAR	(1 ml)		QUESTCOR
Feeling abnormal	ACIDOPHILUS	C				
Heart rate increased	FOLIC ACID	C				
	XANAX	C				
	AZMACORT	C				
	IBUPROFEN	C				
	NAPROSYN	C				
	SYNTHROID	C				
	RITUXAN	C				
	LANOXIN	C				
	VIT D 3	C				
	VIT B	C				
	VIT E	C				
	IMITREX	C				
	RESTASIS	C				
Asthenia						
Blood pressure increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Sep-2013	9516520	DIRECT		DE		69 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sepsis	ACTHAR HP	S	SUBCUTANEOUS			QUESTCOR
Cellulitis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Sep-2013	9475464	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0274	60 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Faeces discoloured	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	SUBCUTANEOUS	80 units, biw, Subcutaneous		
	HUMALOG (INSULIN LISPRO)	C				
	TRAMADOL (TRAMADOL)	C				
	CARDIAZEM (DILTIAZEM)	C				
	WELCHOL (COLESEVELAM HYDROCHLORIDE) (625 MILLIGRAM, TABLET) (COLESEVELAM HYDROCHLORIDE)	C				
	LISINOPRIL (LISINOPRIL)	C				
	DHEA (PRASTERONE)	C				
	CALCIUM WITH VITAMIN D (CALCIUM CARBONATE, COLECALCIFEROL)	C				
	PREDNISONE (PREDNISONE)	C				
	NEXIUM (ESOMEPRAZOLE MAGNESIUM)	C				
Abdominal pain						
Gastrointestinal haemorrhage						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
12-Sep-2013	9523789	DIRECT	Y	HO		82 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Deep vein thrombosis	ACTHAR	S	INTRAMUSCULAR			QUESTCOR

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Sep-2013	8337702	NON-EXPEDITED		OT	CN-JNJFOC-20120104193		Unknown	CHN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Infantile spasms	TOPIRAMATE	S	ORAL			
Refusal of treatment by patient	ACTH	S	INTRAVENOUS			
	ACTH	S	INTRAVENOUS			
	IVIG	S	INTRAVENOUS			
	VITAMIN B6	S	INTRAVENOUS			
	PREDNISONE	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Sep-2013	9529176	NON-EXPEDITED		HO	US-LUNDBECK-DKLU1089070	4 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal distension	Onfi	S				LUNDBECK
Lethargy	SABRIL (TABLET)	S				LUNDBECK
Constipation	HP ACTHAR	S	OTHER			
	HP ACTHAR	S	OTHER	30 UNITS DAILY		
	LEVETIRACETAM	S				
	RANITIDINE HYDROCHLORIDE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Sep-2013	9530712	DIRECT		OT		24 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abdominal pain upper	ACTHAR	S	SUBCUTANEOUS	80 units daily x5 days SQ	5 DAY	QUESTCOR
Abdominal discomfort						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Sep-2013	9528060	EXPEDITED (15-DAY)		OT	CN-JNJFOC-20130907083		Unknown	CHN

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Developmental delay	TOPIRAMATE	S	ORAL	25 to 200 mg per day (3.57 to 20 mg/kg/day		
Drug ineffective	TOPIRAMATE	S	ORAL	0.5 to 1 mg/kg/day		
Convulsion	VALPROIC ACID	S	UNKNOWN			
Off label use	CLONAZEPAM	S	UNKNOWN			
Decreased appetite	NITRAZEPAM	S	UNKNOWN			
Somnolence	PHENYTOIN	S	UNKNOWN			
Hypohidrosis	CARBAMAZEPINE	S	UNKNOWN			
Pyrexia	LEVETIRACETAM	S	UNKNOWN			
Fatigue	ACTH	S	UNKNOWN			
Insomnia	PREDNISONE	S	UNKNOWN			
Temperature intolerance						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Sep-2013	9552144	DIRECT	Y			63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Musculoskeletal stiffness	ACTHAR	S				
Pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Sep-2013	9562363	DIRECT	Y			69 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Incorrect dose administered	ACTHAR	S	INTRAMUSCULAR	1ml twice weekly, im.	1 MTH	
Underdose						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Sep-2013	9570828	EXPEDITED (15-DAY)	Y	DE,HO	QSC-2013-0327	42 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cerebrovascular accident	H.P. ACTHAR GEL	S	SUBCUTANEOUS	80 UNITS, QW, SUBCUTANEOUS		
	CELLCEPT (MYCOPHENOLATE MOFETIL)	C				
	PREDNISONE (PREDNISONE)	C				
	SYNTHROID (LEVOTHYROXINE SODIUM)	C				
	LASIX (FUROSEMIDE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Oct-2013	9586029	DIRECT	Y			59 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Oedema	ACTHAR	S		40 U	2 MTH	

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
03-Oct-2013	9592560	DIRECT	Y	HO		72 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood glucose increased	ACTHAR	S				QUESTCOR

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Oct-2013	9596839	EXPEDITED (15-DAY)		OT	US-US-EMD SERONO, INC.-7227598		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood glucose increased	REBIF	S	SUBCUTANEOUS			
Swelling face	REBIF	S	SUBCUTANEOUS			
Tremor	ACTHAR	S				
Injection site bruising						
Injection site scar						
Multiple sclerosis relapse						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Oct-2013	9607583	DIRECT		HO,DS,LT		66 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspnoea	ACTHAR	S	INTRAMUSCULAR	1 mL two times a week inject, --, Into the muscle		QUESTCOR
Alopecia						
Blood calcium abnormal						
Blood cholesterol increased						
Blood magnesium abnormal						
Blood potassium abnormal						
Blood pressure abnormal						
Cataract						
Deafness						
Diabetes mellitus						
Immune system disorder						
Muscular weakness						
Nail disorder						
Rotator cuff syndrome						
Skin wrinkling						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Oct-2013	9615343	DIRECT	Y	OT		45 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	ACTHAR GEL 80 UNITS/ML	S		80 units, twice a week, subcutaneous		QUESTCOR

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Oct-2013	9616604	DIRECT	Y	HO		58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ulcer haemorrhage	ACTHAR	S	SUBCUTANEOUS			
Helicobacter infection						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Oct-2013	9109038	EXPEDITED (15-DAY)		HO	US-UCBSA-078731	4 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Constipation	LEVETIRACETAM	S				
Abdominal distension	H. P. ACTHAR GEL	S	SUBCUTANEOUS			
Lethargy	H. P. ACTHAR GEL	S	SUBCUTANEOUS	TAPERED DAILY DOSE : 30 UNITS		
	VIGABATRIN	S				
	CLOBAZAM	S				
	RANITIDINE HYDROCHLORIDE	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Oct-2013	8473424	EXPEDITED (15-DAY)	Y	DE,HO,OT	QSC-2012-0015	56 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Asthenia	H.P. ACTHAR	S	SUBCUTANEOUS	80 units, biw, Subcutaneous		
	PROGRAF	S	ORAL	500 mg, bid, oral		
Acute respiratory distress syndrome	CELLCEPT	S	ORAL			
	SIMVASTATIN	C				
Pneumonia	LOVAZA	C				
Fungal infection						
Incorrect drug administration duration						
Sensation of heaviness						
Skin lesion						
Weight decreased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Oct-2013	9630650	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0339	54 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Malignant hypertension	H.P. ACTHAR	S	SUBCUTANEOUS	40 units, qw, Subcutaneous		
Cardiac failure congestive	LASIX (FUROSEMIDE)	C				
Anaemia of chronic disease	COZAAR (LOSARTAN POTASSIUM) (50 MILLIGRAM, TABLETS) (LOSARTAN POTASSIUM)	C				
Treatment noncompliance	CARDURA (DOXAZOSIN MESILATE)	C				
Blood glucose increased	CARVEDILOL (CARVEDILOL)	C				
	LANTUS (INSULIN GLARGINE)	C				
	NOVOLOG (INSULIN ASPART)	C				
	LIPITOR (ATORVASTIN CALCIUM)	C				
	NEXIUM I.V.	C				
	VICTOZA (LIRAGLUTIDE)	C				
Local swelling						
Pericardial effusion						
Renal failure acute						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Oct-2013	9630656	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0362	18 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pleural effusion	H.P. ACTHAR	S	SUBCUTANEOUS	80 units, biw, Subcutaneous		
Nephrotic syndrome	CYCLOSPORINE (CICLOSPORIN)	C				
Fluid overload						
Treatment failure						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Oct-2013	9630665	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0363	60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Ischaemic stroke	H.P. ACTHAR	S	SUBCUTANEOUS	40 units, biw, Subcutaneous		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Oct-2013	9640371	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0361	39 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Intracranial pressure increased	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	SUBCUTANEOUS			
Papilloedema	LISINOPRIL (LISINOPRIL)	C				
Paraesthesia	LISINOPRIL (LISINOPRIL)	C				
Headache	IBUPROFEN (IBUPROFEN)	C				
Blood pressure increased	AVONEX (INTERFERON BETA-1A)	C				
Asthenopia						
Epistaxis						
Hyperacusis						
Musculoskeletal stiffness						
Photopsia						
Visual impairment						
Weight increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Oct-2013	9651025	DIRECT	Y	HO		81 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypersensitivity	ACTHAR HP	S	SUBCUTANEOUS			QUESTCOR

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Nov-2013	9671172	DIRECT		HO,LT		61 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Lethargy	ACTHAR	S				QUESTCOR
Blood pressure decreased						
Body temperature increased						
Dyspnoea						
Feeling abnormal						
Hyperhidrosis						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Nov-2013	9640359	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0360	65 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Renal failure chronic	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	SUBCUTANEOUS	80 units, biw, subcutaneous		
Fluid overload	RAPAMUNE (SIROLIMUS)	C				
Postoperative ileus	CELLCEPT (MYCOPHENOLATE MOFETIL) TABLET	C				
Dialysis	METHIMAZOLE (THIAMAZOLE)	C				
Weight increased	AMLODIPINE (AMLODIPINE)	C				
	ASPIRIN (ACETYLSALICYLIC ACID)	C				
	ATORVASTATIN (ATORVASTATIN)	C				
	CALCIUM CARBONATE (CALCIUM CARBONATE)	C				
	CARVEDILOL (CARVEDILOL)	C				
	DOCUSATE SODIUM (DOCUSATE SODIUM)	C				
	FLUTICASONE)FLUTICASONE)	C				
	LORTAB (HYDROCODONE BITARTRATE, PARACETAMOL)	C				

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	LANTUS)INSULIN GLARGINE)	C				
	NEPHRON FA (ASCORBIC ACID, BIOTIN, CALCIUM PANTOTHENATE, CYANOCOBALAMIN, DOCUSATE SODIUM, FERROUS FUMARATE, FOLIC, NICOTINAMIDE, PYRIDOXINE, HYDROCHLORIDE, RIBOFLAVIN, THIAMINE HYDROCHLORIDE)	C				
	ESOMEPRAZOLE (ESOMEPRAZOLE)	C				
	TACROLIMUS (TACROLIMUS)	C				
	MIRALAX	C				
	FLOMAX (TAMSULOSIN HYDROCHLORIDE)	C				
Abdominal wall haemorrhage						
Dyspnoea						
Fluid retention						
Oedema						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Nov-2013	9690612	DIRECT	Y	OT		53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Migraine	ACTHAR	S	SUBCUTANEOUS	100 units QD SUBCUTANEOUS		
Palpitations	BACLOFEN	C				
	ASA	C				
	PERCOCET	C				
Flushing						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
15-Nov-2013	9692621	DIRECT		OT		68 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Joint swelling	ACTHAR HP	S		Injectable, Diagnosis: 340		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
25-Nov-2013	9718328	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0421		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Pulmonary embolism	H.P. ACTHAR	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
02-Dec-2013	9722567	EXPEDITED (15-DAY)		HO,OT	US-UCBSA-104409		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abnormal behaviour	VIMPAT	S				
Convulsion	KEPPRA	S				
Psychotic disorder	PREDNISONE	S				
Sepsis	VIGABATRIN	S				
Hypersomnia	CLONAZEPAM	S				
Walking disability	TOPOMAX	S				
Muscle atrophy	ZONEGRAN	S				
Emotional disorder	LAMICTAL	S				
Cognitive disorder	BANZEL	S				
Sleep terror	ACTH	S				
Asthenia						
Crying						
Decreased appetite						
Drug ineffective						
Fall						
Psychomotor skills impaired						
Screaming						
Sleep disorder						
Status epilepticus						
Weight increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Dec-2013	9752315	DIRECT	Y	OT		69 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspnoea	ACTHAR	S	SUBCUTANEOUS			QUESTCOR

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
11-Dec-2013	9752868	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0439	26 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Orthostatic hypotension	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S		60 units, BIW		
Vomiting	PREDNISONE	C				
Postural orthostatic tachycardia syndrome	MARINOL	C				
Gastrooesophageal reflux disease	LANTUS (INSULIN GLARGINE)	C				
Gastrointestinal disorder	ZOFRAN (ONDANSETRON)	C				
	PHENERGAN (PROMETHAZINE)	C				
	DIAMOX (ACETAZOLAMIDE)	C				
	CALCIUM & VITAMIN D (CALCIUM, COLECALCIFEROL)	C				
	FLEXERIL (CYCLOBENZAPRINE HYDROCHLORIDE)	C				
	BENTYL (DICYCLOVERINE HYDROCHLORIDE)	C				
	VITAMIN D2 (ERGOCALCIFEROL)	C				
	NOVOLOG (INSULIN ASPART)	C				
	ATIVAN (LORAZEPAM)	C				
	PROTONIX (PANTOPRAZOLE SODIUM SESQUIHYDRATE)	C				
	CARAFATE (SUCRALFATE) TABLET, 1G	C				
	IMITREX (SUMATRIPTAN)	C				
	VENTOLIN (SALBUTAMOL)	C				
	ALBUTEROL (SALBUTAMOL SULFATE)	C				
	DONNATAL (ATROPINE SULFATE, HYOSCINE HYDROBROMIDE, HYOSCYAMINE SULFATE, PHENOBARBITAL)	C				
	ZYRTEC (CETIRIZINE HYDROCHLORIDE)	C				
	EPIPEN (EPINEPHRINE)	C				

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	GLUCAGON (GLUCAGON)	C				
	PROAMATINE (MIDODRINE HYDROCHLORIDE)	C				
	LISINOPRIL (LISINOPRIL)	C				
	LASIX (FLUROSEMIDE)	C				
Adrenal disorder						
Autonomic nervous system imbalance						
Diarrhoea						
Nausea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Dec-2013	9766353	DIRECT	Y	OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Mood altered	ACTHAR GEL	S		8 units twice weekly, IM		QUESTCOR
Insomnia						
Weight increased						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
23-Dec-2013	9781031	DIRECT		HO,DS		49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	H.P. ACTHAR	S		Given into/inder the skin		QUESTCOR
Amnesia						
Asthenia						
Blood glucose increased						
Blood pressure increased						
Dehydration						
Diarrhoea						
Disturbance in attention						
Dizziness						
Dry eye						
Dry mouth						
Eye irritation						
Fatigue						
Feeling abnormal						
Heart rate increased						
Hyperhidrosis						
Insomnia						
Mood swings						
Myositis						
Nausea						
Photosensitivity reaction						
Psychomotor hyperactivity						
Thirst						
Tremor						
Vision blurred						
Weight fluctuation						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
31-Dec-2013	9792144	DIRECT	Y	OT		57 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	ACTHAR	S	SUBCUTANEOUS		5 MTH	QUESTCOR
Kidney transplant rejection						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Jan-2014	9802918	DIRECT	Y	OT		72 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	ACTHAR GEL	S	SUBCUTANEOUS	80units 2 x weekly Subcutaneous		QUESTCOR
Abdominal distension						
Local swelling						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Jan-2014	9818043	DIRECT	Y			51 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug ineffective	H.P. ACTHAR	S	SUBCUTANEOUS	80 units qd x5ds sc	5 DAY	QUESTCOR

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Jan-2014	9823314	EXPEDITED (15-DAY)		HO	US-LUNDBECK-DKLU1093316	281 DAY	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Brain injury	Sabril (For Oral Solution)	S	ORAL			LUNDBECK
Hypertension	Sabril (For Oral Solution)	S	ORAL			LUNDBECK
Choreoathetosis	Sabril (For Oral Solution)	S	ORAL			
Nuclear magnetic resonance imaging abnormal	Sabril (For Oral Solution)	S	ORAL			
Status epilepticus	Sabril (For Oral Solution)	S	ORAL			
Respiratory failure	Sabril (For Oral Solution)	S	ORAL			
	Sabril (For Oral Solution)	S	ORAL			
	ACTH	S				
	ACTHAR HP	C				
	KEPPRA	C				
	PRILOSEC	C				
	TYLENOL	C	ORAL			
	D-VI-SOL	C	ORAL			
	MIRALAX	C		1 TSP		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Jan-2014	9840593	DIRECT		OT		40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Face oedema	ACTHAR	S			3 MTH	
Pyrexia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2014	9643254	EXPEDITED (15-DAY)	Y	HO,OT	QSC-2013-0373	182 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cardiomyopathy	H.P.ACTHAR	S		unk		
	VIGABATRIN (VIGABATRIN)	C				
	DIFLUCAN (FLUCONAZOLE)	C				
	OMNICEF (CEFDINIR)	C				
	ZANTAC (RANITIDINE HYDROCHLORIDE)	C				
	KLONOPIN (CLONAZEPAM) (TABLETS)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2014	9852357	EXPEDITED (15-DAY)	Y	OT	QSC-2014-0040		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Brain abscess	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S				
	CELLCEPT (MYCOPHENOLATE MOFETIL) TABLET	S	ORAL			

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2014	9852377	EXPEDITED (15-DAY)	Y	HO	QSC-2013-0142	152 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Medication error	H.P. ACTHAR	S	INTRAMUSCULAR	80 units, qd for 2 weeks, Intramuscular		
	PRILOSEC (OMEPRAZOLE)	C				
Hypertension						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2014	9852386	EXPEDITED (15-DAY)	Y	HO	QSC-2012-0314	63 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dyspnoea	H.P. ACTHAR GEL	S		80 Units, BIW		
Dyspnoea	DIVOAN (VALSARTAN)	C				
	(BISOLICH (BISOPROLOL FUMARATE)	C				
	GLIMEPIRIDE (GLIMEPIRIDE)	C				
	WELLBUTRIN (BUPROPION HYDROCHLORIDE)	C				
Hypertension						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Jan-2014	9854850	EXPEDITED (15-DAY)	Y	DE	QSC-2014-0029		Unknown	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sepsis	H.P. ACTHAR GEL	S		unk		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Feb-2014	9876248	NON-EXPEDITED			US-ACORDA-ACO_36619_2013	40 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Swelling face	Ampyra	S	UNKNOWN	10 mg, Q 12 hrs		ACORDA
Local swelling	ACTHAR HP	S	UNKNOWN	UNK,UNK		
Erythema	Cyproheptadine HCl	C	UNKNOWN	4 mg, UNK		
Hot flush	Promethazine	C	UNKNOWN	25 mg, UNK		
	Imitrex	C	UNKNOWN	50 mg, UNK		
	Doxepin hcl	C	UNKNOWN	50 mg, UNK		
	Skelaxin	C	UNKNOWN	800 mg, UNK		
	Topamax	C	UNKNOWN	25 mg, UNK		
	Ultram	C	UNKNOWN	50 mg, UNK		
	Gilenya	C	UNKNOWN	UNK,UNK		
	Zanaflex	C		4 mg, UNK		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
06-Feb-2014	9876467	NON-EXPEDITED			US-ACORDA-ACO_35266_2013		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dry mouth	Ampyra	S		10 mg, bid		ACORDA
	ACTHAR HP	S	SUBCUTANEOUS	80 ut/ml, qd		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Feb-2014	9885982	DIRECT	Y			55 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Palpitations	ACTHAR GEL	S	SUBCUTANEOUS	Inject 1ml under the skin every 2 weeks for 6 months, Expires in 28 days once opened;	6 MTH	
Dyspnoea						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Feb-2014	9886008	DIRECT	Y			85 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Local swelling	H.P. ACTHAR	S	SUBCUTANEOUS	inject 80 units (1mL) under the skin twice weekly for 6 months.	6 MTH	QUESTCOR

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Feb-2014	9888860	EXPEDITED (15-DAY)	Y	DE,HO	QSC-2014-0034	58 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Acute respiratory distress syndrome	H.P ACTHAR GEL (ADRENOCORITCOTROPIC HORMONE) GETL FOR INJECTION, 80 U/ML	S	SUBCUTANEOUS	80 units, biw, Subcutaneous		
Respiratory failure	MEDROL (METHYLPREDNISOLONE)	C				
Shock	PROAIR HFA (SALBUTAMOL SULFATE)	C				

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Atrial fibrillation	PREDNISONE(PREDNISONE)	C				
	FUROSEMIDE(FUROSEMIDE)	C				
Anaemia	PROTONIX(PANTOPRAZOLE SODIUM SESQUIHYRATE)	C				
Bundle branch block left	ZYRTEC(CETIRIZINE HYDROCHLORIDE)	C				
	FERROUS SULFATE(FERROUS SULFATE)	C				
	ACETAMINOPHEN (PARACETEMAOL)	C				
	CULTURELLE(LACTOBACILLUS NOS)	C				
	FOLIC ACID (FOLIC ACID)	C				
	MULTIVITMAIN (VITAMINS NOS)	C				
	SUPER B COMPLEX (VITAMIN B COMPLEX)	C				
	VITAMIN D NOSE (VITAMIN D NOS)	C				
	ZITHROMAX(AZITHROMYCIN)	C				
	ADVAIR(FLUTICASONE PROPRIONATE, SALMETEROL XINAFOATE)	C				
	BENADRYL(DIPHENHYDRAMINE HYDROCHLORIDE)	C				
	PREVAGEN	C				
	ELOCON CREAM (MOMETASONE FUROATE CREAM)	C				
Extremity necrosis						
Lactic acidosis						
Pneumonia aspiration						
Respiratory arrest						
Skin necrosis						
Thrombocytopenia						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Feb-2014	9667605	EXPEDITED (15-DAY)		HO	US-LUNDBECK-DKLU1094374	270 DAY	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Gastroenteritis	Sabril (For Oral Solution)	S	ORAL			LUNDBECK
Hypertension	Sabril (For Oral Solution)	S	ORAL			LUNDBECK
Convulsion	Sabril (For Oral Solution)	S	ORAL			
Haematuria	Sabril (For Oral Solution)	S				
Tympanic membrane perforation	ACTH	S				
Irritability	TOPAMAX	C				
Somnolence	PRELONE	C				
Otitis media acute	NORVASC	C				
Upper respiratory tract infection	PREDNISOLE	C				
	ZONEGRAN	C				

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2014	9915629	DIRECT		DS		53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Blood glucose increased	ACTHAR HP	S	SUBCUTANEOUS	400 usp units/5ml (80usp units/ml 1 shot daily for 5 days. 1mL once daily for 5 days subcutaneous injection	5 DAY	QUESTCOR
	METOPROLOL SUCC ER	C				
Vision blurred	LOVAZA	C				
Weight increased	CITRACAL	C				
Confusional state	VIT D	C				
	CITOLPRAM	C				
	BACLFEN	C				
	VITAFUSION MULTI. VIT	C				
	VIT. C.	C				
	TECFIDER	C				
	FUROSEMIDE	C				
	FUROSEMIDE	C				
	VIT D3	C				
	BENEDRYL	C				
	VIPAFUSION MULTI-VITAMINS CHEWABLE 2 GUMMIES	C				
	RECLAST	C				
	NIACIN	C				
	VIT B COMPLETE WITH B12	C				
Back pain						
Muscle spasms						
Vaginal haemorrhage						
Visual impairment						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Feb-2014	9916030	EXPEDITED (15-DAY)	Y	HO	QSC-2014-0087	61 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Acute myocardial infarction	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S		UNK		
Anaemia						
Asthenia						
Herpes zoster						
Pneumonia bacterial						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Feb-2014	9959411	DIRECT		HO		75 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Local swelling	ACTHAR GEL HP80UNIT/ML 5ML VL QUESTCOR	S	SUBCUTANEOUS	inject 1 ml (80 units) subcutaneously twice a week for 12 weeks.	12 WEEK	QUESTCOR
Blood pressure increased						
Dizziness						
Headache						
Hypoaesthesia						
Paraesthesia oral						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
28-Feb-2014	9959457	DIRECT				60 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Speech disorder	ACTHAR GEL HP80UNIT/ML 5ML VL QUESTCOR PHARM.	S	SUBCUTANEOUS	subcutaneously twice a week for 6 chronic membranous month		QUESTCOR
Arthralgia						
Pain in extremity						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
04-Mar-2014	9971333	EXPEDITED (15-DAY)	Y	OT	QSC-2014-0112	49 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
	H.P ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE), GEL FOR INJECTION, 80U/ML	S	SUBCUTANEOUS			
Atrial fibrillation	CANDESARTAN (CANDESARTAN)	C				
	FISH OIL (FISH OIL)	C				
	NIACIN (NICOTINIC ACID)	C				
	ALLEGRA	C				
Oedema						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Mar-2014	9971472	DIRECT				422 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Insomnia	H.P. ACTHAR	S	SUBCUTANEOUS	80 ML once daily Given into/Under the skin		QUESTCOR
Abdominal distension						
Dyspnoea						
Local swelling						

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FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Mar-2014	9983447	EXPEDITED (15-DAY)		HO,OT	US-LUNDBECK-DKLU1097930	1 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hypertension	Sabril (For Oral Solution)	S	ORAL			LUNDBECK
Renal disorder	Sabril (For Oral Solution)	S	ORAL			LUNDBECK
Gastrointestinal infection	Sabril (For Oral Solution)	S	ORAL			
Convulsion	Sabril (For Oral Solution)	S	ORAL			
Clumsiness	Sabril (For Oral Solution)	S	ORAL			
Dizziness	Sabril (For Oral Solution)	S	ORAL			
	ACTHAR	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
07-Mar-2014	9994734	DIRECT	Y	OT			Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Adverse drug reaction	ACTHAR	S		previous use unknown, unknown, unknown		QUESTCOR
	ALPRAZOLAM	C				
	AZITHROMYCIN	C				
	CALCITRATE	C				
	CHLORDIAZEPOXIDE/AMIT	C				
	D-AMPHETAMINE SALTS	C				
	DICYCLOMINE	C				
	CIPROFLOXACIN	C				
	FLUCONAZOLE	C				
	LEVOFLOXACIN	C				
	LEVOTHYROXINE	C				
	METOCLOPRAMIDE	C				
	MONTELUKAST	C				
	MUPIROCIN 2% OINTIMENT	C				
	NITROFURANTOIN MON/MAC	C				
	OMEPRAZOLE	C				
	OMNARIS	C				
	ONDANSETRON ODT	C				
	PANTOPRAZOLE	C				
	PREDNISONE	C				
	PROMETHAZINE	C				
	PROPRANOLOL	C				
	SUPREP BOWEL PREP SOLUTION	C				
	TAMIFLU	C				
Product quality issue						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
10-Mar-2014	9999041	EXPEDITED (15-DAY)	Y	HO	QSC-2014-0101	73 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Syncope	H.P. ACTHAR GEL	S				
Hiccups						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
13-Mar-2014	10011636	DIRECT	Y	OT		63 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Headache	ACTHAR H.P.	S	SUBCUTANEOUS	80units/ml Injectable Subcutaneous 057 twice weekly		
Abdominal pain						
Wheezing						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Mar-2014	10013004	NON-EXPEDITED		OT	US-PFIZER INC-2014071294	36 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Fluid retention	Lyrica	S		UNK		PFIZER
Dyspnoea	CYCLOSPORINE	S		UNK		
Muscle twitching	H.P ACTHAR GEL	S		UNK		
	H.P ACTHAR GEL	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
14-Mar-2014	10025647	EXPEDITED (15-DAY)	Y	HO	QSC-2014-0133	55 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Renal failure acute	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	SUBCUTANEOUS			
Syncope	METOLAZONE (METOLAZONE)	C				
Hypokalaemia	LASIX (FUROSEMIDE)	C				
Dehydration	METFORMIN (METFORMIN)	C				
Decreased appetite	LISINOPRIL (LISINOPRIL)	C				
Acute prerenal failure						
Dysgeusia						
Fatigue						
Renal failure acute						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
18-Mar-2014	10022179	DIRECT		OT		34 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Underdose	ACTHAR H.P.	S	ORAL	80u/ml oral 047 twice weekly		
No adverse event	PREDNISONE	C				
	ARAVA	C				
	TRILEPTAL	C				
Wrong technique in drug usage process						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Mar-2014	10029784	EXPEDITED (15-DAY)		HO	QSC-2014-0143		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Renal failure	H.P. ACTHAR GEL	S	SUBCUTANEOUS			
Dialysis						
Oedema						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
19-Mar-2014	9999039	EXPEDITED (15-DAY)	Y	OT	QSC-2014-0124	26 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Central nervous system lesion	H.P. ACTHAR GEL	S	SUBCUTANEOUS	unk, 10 days		
	DIMETHYL FUMARATE	C				
Paraesthesia						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
20-Mar-2014	10029837	EXPEDITED (15-DAY)	Y	HO	QSC-2014-0142	23 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Dehydration	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S				
Blood creatinine increased						
Nausea						
Vomiting						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
21-Mar-2014	10027909	EXPEDITED (15-DAY)		OT	US-SA-2013SA103272	36 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Abasia	AUBAGIO	S	ORAL			
Hot flush	ACTHAR	S	UNKNOWN			
Alopecia						
Multiple sclerosis relapse						
Pain in extremity						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
26-Mar-2014	10039409	EXPEDITED (15-DAY)		OT	PHHY2014US036042		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Neuromyelitis optica	MYCOPHENOLATE	S				NOVARTIS
Drug ineffective	AZATHIOPRINE	S				
	GLATIRAMER ACETATE	S				
	INTERFERONS	S				
	ACTH	S				
	RITUXIMAB	S				
	MITOXANTRONE	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Mar-2014	10040894	NON-EXPEDITED		OT	US-PFIZER INC-2014085285	79 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Drug hypersensitivity	ERYTHROMYCIN	S		UNK		PFIZER
	TRIMETHOPRIM	S		UNK		UNKNOWN
	PHENOBARBITAL	S		UNK		
	ACTH	S		UNK		
	DRIXORAL	S		UNK		
	FLURAZEPAM HYDROCHLORIDE	S				
	DICYCLOVERINE HYDROCHLORIDE	S				
	CHLORPHENAMINE W/ PHENYLPROPANOLAMINE	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
27-Mar-2014	10048409	EXPEDITED (15-DAY)	Y	DE	QSC-2014-0141	67 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sudden death	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	SUBCUTANEOUS			
Abdominal pain						
Fluid retention						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Apr-2014	10056129	EXPEDITED (15-DAY)		HO	QSC-2014-0179	48 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Incorrect route of drug administration	H.P. ACTHAR GEL	S				
Anxiety						
Heart rate increased						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
01-Apr-2014	10056142	EXPEDITED (15-DAY)	Y	HO	QSC-2014-0187		Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Sepsis	H.P. ACTHAR GEL	S				
	RITUXAN (RITUXIMAB)	C				
	IMMUNOGLOBULIN (IMMUNOGLOBULINS NOS)	C				
	METHOTREXATE (METHOTREXATE)	C				
	PREDNISONE (PREDNISONE)	C				
	CYCLOPHOSPHAMIDE (CYCLOPHOSPHAMIDE)	C				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Apr-2014	10072553	EXPEDITED (15-DAY)	Y	HO	QSC-2014-0212		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Diabetic ketoacidosis	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S				

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Apr-2014	9845585	EXPEDITED (15-DAY)	Y	HO	QSC-2014-0011	29 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Haemoglobin decreased	H.P. ACTHAR GEL	S				
Heart rate increased	CYMBALTA (DULOXETNE HYDROCHLORIDE)	C				
Haematochezia	METHOTREXATE (METHOTREXATE)	C				
Dyspnoea	FOLIC ACID (FOLIC ACID)	C				
Abdominal pain						
Anaemia						
Gastrointestinal haemorrhage						
Pain						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
09-Apr-2014	9971318	EXPEDITED (15-DAY)	Y	OT	QSC-2014-0106	12 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Tachycardia	H.P. ACTHAR GEL	S	SUBCUTANEOUS			
Toxicity to various agents	MEDROL (METHYLPREDNISOLONE ACETATE)	C				
	SOLUMEDROL (METHYLPREDNISOLONE SODIUM)	C				
	VORICONAZOLE (VORICONAZOLE)	C				
	VALCYTE (VALGANCICLOVIR HYDROCHLORIDE) (VALGANCICLOVIR HYDROCHLORIDE)	C				
Drug interaction						

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Apr-2014	10085726	EXPEDITED (15-DAY)	Y	HO	QSC-2014-0232	54 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Renal failure	H.P. ACTHAR GEL (ADRENOCORTICOTROPIC HORMONE) GEL FOR INJECTION, 80U/ML	S	SUBCUTANEOUS			
Drug effect incomplete						
Fluid overload						
Fluid retention						

FDA Adverse Event Reporting System (FAERS)
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Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
16-Apr-2014	10086295	EXPEDITED (15-DAY)	Y	DE,HO	QSC-2014-0233	54 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Cardiac failure	H.P ACTHAR GEL	S				
Pneumonia						
Weight increased						