

Spontaneous UK Suspected Adverse Drug Reaction (ADR) Reports for Echinacea (Child Cases)

These reports relate to Yellow Cards received directly from healthcare professionals and patients and does not include reports from pharmaceutical companies

Extract Period	01/07/1963 - 31/01/2012
Run Date	16/02/2012

Table 1: Aggregated patient data (Child*):

Patient Sex	Total
Female	4
Male	2
Unknown	1
	7

Patient Age	Total
< 18	7
	7

**Please note that the children are aged 16 years and younger.*

Table 2: Echinacea Child Cases

Case ID	Suspect Drugs (Indication)	Other Drugs	Reactions (Outcome)	Case Narrative	Date Received
1	ECHINACEA [Bioforce Echinacea complex] (Cough)	BECLOMETHASONE, SALBUTAMOL	Urticaria (Recovered/resolved)	The patient experienced urticaria the day Echinacea was started. Patient was treated with piriton and calpol and was admitted to hospital. Patient recovered the next day.	2003
2	ECHINACEA (Upper respiratory tract infection)		Idiopathic thrombocytopenic purpura (Recovered/resolved)	Echinacea given for two months prior to Idiopathic thrombocytopenic purpura (ITP) diagnosis. Bruising noticed and found to be ITP. Platelet count 6. No significant medical history.	2001
3	Roberts Golden Seal [chamomile flower, Golden seal root, Marshmallow root, Poke root & Echinacea] (Colitis ulcerative)	Ferrous sulphate	Weight increased (Unknown)	Massive weight gain, possible Cushingoid. The patient has a history of Ulcerative colitis (currently asymptomatic) and headaches. The General Practitioner (GP) was concerned about the patient's appearance during a visit to discuss the patient's headaches. The patient had put on a considerable amount of weight in the previous year, increasing from 39kg to approx 58kg. It is uncertain when the patient started Roberts Golden Seal but GP was concerned in case the herbal product may contain a steroid due to patient's cushingoid appearance. Herbal product stopped, dietary advice given. Follow up GP visits indicated headaches had stopped and weight had leveled off but patient was still obese.	2001
4	ECHINACEA, PREDNISOLONE (Wheezing)		Confusional state (Unknown)	Patient was taking echinacea for approximately two weeks. Patient was then prescribed prednisolone for wheeziness and within a couple of hours was confused and talking gibberish.	2003
5	ECHINACEA [Echinaforce]		Aplastic anaemia (Not recovered/not resolved)	One month after starting Echinaforce patient was found to have life-threatening aplastic anaemia. No other cause has been found for the aplastic anaemia. Investigations indicate idiopathic aplastic anaemia which required in-patient treatment.	2000

6	ECHINACEA [Benylin Active Response] (Oropharyngeal pain)		Angioedema (Recovered/resolved)	Angioedema after one dose, treated with intravenous hydrocortisone and chlorpheniramine. Benylin Active Response was self prescribed for sore throat. The patient had no known allergies.	2002
7	ECHINACEA [Benylin Active Response] (Fatigue)		Dysphagia (Recovered/resolved), Dyspnoea (Recovered/resolved), Face oedema (Recovered/resolved), Tongue oedema (Recovered/resolved)	Patient took benylin active response once and experienced angioedema with difficulty swallowing and breathing. Patient was treated with intravenous steroids and antihistamines. The events resolved the same day.	2002

Please note the following:

The inclusion of a particular reaction on our system does not necessarily mean that it has been caused by the drug. Many factors have to be taken into account in assessing causal relationships including temporal association, the possible contribution of concomitant medication, and the underlying disease.

The Commission on Human Medicines (CHM) and MHRA encourage the use of data collected through the Yellow Card Scheme in publications. However, we wish to ensure correct interpretation has been placed on the data, taking into account the limitations of spontaneous ADR reporting. For this reason, should you wish to publish any of the above mentioned data I would be grateful if you could submit the proposed manuscript for approval. We will endeavour to respond to all requests within 1-2 working days.

Spontaneous UK Suspected Adverse Drug Reaction (ADR) Reports for Echinacea (Adult Cases)

These reports relate to Yellow Cards received directly from healthcare professionals and patients and does not include reports from pharmaceutical companies

Extract Period	01/07/1963 - 31/01/2012
Run Date	16/02/2012

Table 1: Aggregated patient data (Adult):

Patient Sex	Total
Female	27
Male	11
Unknown	2
	40

Patient Age	Total
18-24	3
25-34	6
35-44	7
45-54	6
55-64	9
65-74	7
75-84	1
> 84	0
Unknown	1
	40

Table 2: Echinacea Adult Cases

Case ID	Suspect Drugs (Indication)	Other Drugs	Reactions (Outcome)	Case Narrative	Date Received
8	ASPARAGUS (Constipation), BEETROOT EXTRACT (Constipation), CYNARA (Constipation), ECHINACEA (Constipation), MATRICARIA (Constipation)	CETIRIZINE, CYPROTERONE AND ETHINYLOESTRADIOL, FOENICULUM VULGARE, FRANGULA, PLANTAGO, SALBUTAMOL, SAMBUCUS NIGRA, SENNA	Dizziness (Recovered/resolved), Dyspnoea (Recovered/resolved), Rash (Recovered/resolved)	Medically significant: Shortness of breath, difficulty breathing, lightheaded, rash on chest immediately after taking medication.	2009
9	ALTHAEA AND ECHINACEA AND SAMBUCUS NIGRA	ETHINYLOESTRADIOL AND LEVONORGESTREL	Urticaria (Unknown)	Urticaria requiring intravenous Piriton and steroids at local Accident and Emergency Department.	1997
10	ECHINACEA		Condition aggravated (Unknown), Optic nerve disorder (Unknown), Sarcoidosis (Unknown), Visual acuity reduced (Unknown), White blood cell count increased (Unknown)	I had no idea that I had a disease called sarcoidosis. Echinacea caused a boost in an already unsteady immune system causing an over production of white blood cells to form in my right eye which have permanently damaged my optic nerve and left me partially sighted in that eye. I realised after diagnosis that I had some symptoms of sarcoidosis for the previous year and a half but I had managed.	2006

11	ACACIA, ALTHAEA, CARUM, ECHINACEA, SAMBUCUS NIGRA		Coordination abnormal (Recovered/resolved), Vision blurred (Recovered/resolved)	Vision blurred after ten mins of taking, incoordinated limbs, therefore panic. Reaction lasted a full 12 hours. Suspect drug stated to be Boots Herbal Catarrh Tablets. Ingredients: Marshmallow root 80mg; Echinacea 75 mg; Elderflower 50mg; sucrose; calcium carbonate; parsley root powder; talc; calcium phosphate; acacia; maize starch; shellac; titanium dioxide; magnesium stearate; silicon dioxide; iron oxide; carniga wax; beeswax; copper chlorophyllin. The reporter considered the reaction to be serious for the following reason: medically significant - reaction lasted a full 12 hours after taking two tablets.	2001
12	ECHINACEA (Nasopharyngitis), WARFARIN (Aortic valve replacement)		Drug interaction (Recovering/resolving), International normalised ratio increased (Recovering/resolving)	Patient on warfarin for aortic valve replacement. Recurrent colds - started echinacea. International normalised ratio (INR) increased from 2.4 to 7.6 within two days. The reporter considered the reaction to be serious: reasons not stated.	2003
13	ALLIUM SATIVUM (Seasonal allergy), ECHINACEA (Seasonal allergy)		Abdominal pain (Recovered/resolved), Nausea (Recovered/resolved), Vomiting (Recovered/resolved)	Patient admitted with abdominal pain, nausea and vomiting.	2010
14	ECHINACEA	ASCORBIC ACID AND PARACETAMOL AND PHENYLEPHRINE, IMIPRAMINE	Faecal incontinence (Recovered/resolved), Loss of consciousness (Recovered/resolved), Urinary incontinence (Recovered/resolved)	The patient passed out 30 minutes after taking Echinacea. Patient lost control over bodily functions leaving the patient all the more shaken. The reporter considered the reaction to be serious for the following reason: medically significant. No known allergies.	2004
15	ECHINACEA	CO-AMOXICLAV	Basedow's disease (Recovered/resolved)	Autoimmune hyperthyroidism. Presented with distortion of vertical lines in right visual field of right eye, confirmed as a central serous retinopathy causing macular oedema. Settled gradually over approximately 6 weeks. Patient presented with right proptosis. Graves disease, confirmed by a Thyroid-stimulating Hormone (TSH) antibody titre raised to 23u with negative antithyroid peroxidase Elisa test.	1998
16	ECHINACEA, ESCITALOPRAM (Anxiety), GINKGO BILOBA, VITAMIN B COMPLEX		Agitation (Recovered/resolved), Chills (Recovered/resolved), Drug interaction (Recovered/resolved), Dry throat (Recovered/resolved), Pruritus (Recovered/resolved)	The patient experienced acute agitation, was shivery, had a dry throat and an itch. Reporter stated this could be due to a possible drug interaction. "Homeopathic preparation" is reported as a co-suspect drug.	2004
17	ECHINACEA (Nasopharyngitis)		Eye swelling (Recovered/resolved), Urticaria (Recovered/resolved)	Widespread urticaria. Swollen eyes.	2007
18	BAMBUSA ARUNDINACEA, ECHINACEA (Immune system disorder), HARPAGOPHYTUM, LACTOBACILLUS ACIDOPHILUS	ALLIUM SATIVUM, OMEPRAZOLE, PIZOTIFEN, SUMATRIPTAN	Asthma (Not recovered/not resolved), Urticaria (Not recovered/not resolved)	Developed marked skin reaction which seemed like true urticaria, although in early stages this was associated with some swelling of lips and tongue. Has been on antihistamines and steroids ever since and in spite of that was becoming markedly wheezy 10 days after initial onset of symptoms. Patient does have a history of asthma in past but had not taken any medication or inhalers for this for two or three years. Suspected drugs started - Total doses taken = 5 in 30 hours. Co-suspected drugs: Bamboo gum (Bambousa arundinacea) 270 mg 2 caps 3 x day = 1620 mg/day; Devils claw (Harpagophytum procumbens) 335 mg 2 caps 3 x day = 2010 mg/day; Acidophilus & Bifidus 36 mg 2 caps 3 x day = 216 mg/day. Patient was also taking aromatherapy massage and Bach flower remedy concoctions. Bambousa arundinacea was taken as an anti-inflammatory and for backache. Harpagophytum procumbens was taken as an anti-inflammatory and for joint pains.	1997

19	ECHINACEA, MELISSA, PLANTAGO, Silybum marianum, Solidago, Valeriana officinalis	CARBAMAZEPINE	Dizziness (Recovered/resolved)	Patient did not have a seizure whilst taking the herbal medicine although did experience the same symptoms experienced in the past prior to seizure. Patient felt better on discontinuation of product, I suspect the interaction stemmed predominantly from the use of echinacea as there were many sources stating it interacted with cytochrome p450 metabolised medication in a similar way to St John's Wort. It was asked that the patient fed this information back to their herbalist. Licorice is known to have an inhibitory effect on cytochrome p450. Patient did not have a seizure whilst taking the herbal medicine although did experience the same symptoms had in the past prior to seizure.	2006
20	ECHINACEA	CARBAMAZEPINE, VALPROIC ACID	Epilepsy (Recovering/resolving)	Half an hour after taking had a fit - lasted 5 mins. Repeated next morning. Stopped medication. No further reaction. Suspect drug affected seizure control. Suspect drug - Natures Aid Herbal Range Conc. Echinacea Root equivalent to 500 mg. Taken OTC. The reporter considered the reaction to be serious for the following reason: medically significant: seizure control.	2001
21	ECHINACEA		Dizziness (Recovered/resolved), Irritability (Recovered/resolved), Nausea (Recovered/resolved)	Extreme feeling of nausea, dizziness, faintness and irritability. Concurred with husband who also had similar symptoms and began taking this medicine at around the same time as me (he took no other medication at the same time). We both stopped when we realised that the tablets were the cause and symptoms stopped within a day or two.	2007
22	ECHINACEA, WARFARIN	BECLOMETHASONE, BENDROFLUAZIDE, CODEINE, DICLOFENAC, DOSULEPIN, DOXAPRAM, IRON, NIFEDIPINE, SALBUTAMOL, TRANEXAMIC ACID	Coagulopathy (Recovered/resolved), Drug interaction (Recovered/resolved)	Patient on multiple medications. But previously a normal blood clotting screen. Developed abnormal blood clotting screen after two weeks of treatment with echinacea - settled spontaneously. The reporter considered the reaction to be serious for the following reasons: disability and medically significant - potentially serious interaction.	2003
23	ECHINACEA (Nasopharyngitis)		Parotitis (Recovered/resolved)	Reporter gave no information on the seriousness of the reaction.	2002
24	ECHINACEA		Ventricular arrhythmia (Recovering/resolving)	ECG, 24 hour tape, echocardiogram, exercise tolerance and blood profile were all normal with no ectopics but patient was in sinus rhythm with unifocal ectopics every fourth beat. Patient remains well despite this and will give up smoking. Patient related symptoms to taking echinacea. Two and a half hours after taking it patient felt hot and pulse was irregular. Has taken it before with no ill effects. Patient is generally fit and well. No history of thyroid problems and no obvious goitre. No family history of note. Patient drinks 4 - 5 units alcohol weekly and lots of tea. Rarely smokes.	1999
25	ECHINACEA	ASCORBIC ACID, OENOTHERA, SULPHASALAZINE	Cholangitis sclerosing (Recovering/resolving)	Exacerbation of sclerosing cholangitis. The reporter did not consider the reaction to be serious. Echinacea was self-medicated.	2003
26	ECHINACEA (Immune system disorder)		Liver function test abnormal (Recovering/resolving)	No other drugs.	1998
27	ECHINACEA (Malaise)		Arthralgia (Recovering/resolving), Erythema multiforme (Recovering/resolving)	Patient experienced erythema multiforme type skin rash and arthralgia. Advised to take loratadine. Patient was recovering. Echinacea (OTC HERBAL REMEDY) used for Upper respiratory tract infection with malaise.	2002
28	CHLORPROMAZINE (Hiccups), ECHINACEA (Routine health maintenance)		Cholestasis (Recovering/resolving), Drug interaction (Recovered/resolved), Jaundice (Recovered/resolved)	In hospital for thirty days. Doctors baffled, as every test came back negative. Eventually decided the prescribed chlorpromazine and the oil of echinacea I bought commercially had reacted to cause the jaundice.	2010

29	BORAGO, ECHINACEA	CETIRIZINE, DICLOFENAC, NORETHISTERONE	Pancreatitis acute (Recovering/resolving)	Patient presented with acute pancreatitis. The patient had no significant past medical history or history of alcohol excess. The patient's amylase on admission was 1844, white cell count of 12.1, and blood glucose level of 9.8. Investigations included an ultra sound scan which detected no abnormality and no gallstones, and CT scan which detected pancreatitis, but no necrosis, pseudocyst or abscess. Patient was treated conservatively and was discharged with follow-up arranged with the professional team at hospital for further investigation into the possible etiology of pancreatitis. Patient has been taking diclofenac and norethisterone on and off for the last 5 years without problem. Patient had taken echinacea for about 5 years without problem and had started starflower oil about 5 months ago. Patient changed brands from Boots brand to cheaper alternatives.	2010
30	ECHINACEA	ASPIRIN	Muscle twitching (Recovered/resolved)	Caused twitching in legs two weeks after course started and recovered upon withdrawal of echinacea. The reporter did not consider the reaction to be serious but indicated that the reaction was medically significant - caused twitching in legs. Indications: Family history heart disease (exc ischaemic).	2002
31	ECHINACEA		Swelling (Recovering/resolving)		2006
32	ECHINACEA		Nail discolouration (Not recovered/not resolved)		2008
33	ECHINACEA	PANTOPRAZOLE, SALBUTAMOL	Hypertension (Recovered/resolved)	The reporter considered the reaction to be serious for the following reason: life threatening.	2000
34	ECHINACEA (Influenza like illness)	ASPIRIN, RAMIPRIL, SIMVASTATIN, SOTALOL	Supraventricular tachycardia (Recovered/resolved)	Patient developed acute exacerbation of pre-existing paroxysmal supraventricular tachycardia. Attack of atrial flutter. The reporter considered the reaction to be serious for the following reason: medically significant - possibility of cardiac syncope.	2002
35	ECHINACEA (Immune system disorder)	SACCHAROMYCES	Irritable bowel syndrome (Recovered/resolved)	Patient was taking double the recommended dose. Echinacea tablets stopped and Irritable bowel symptoms (IBS) symptoms stopped. IBS symptoms had been so bad, patient was being investigated for bowel cancer. Echinacea restarted. IBS symptoms returned. The reporter considered the reaction to be serious for the following reason: medically significant - IBS symptoms - bowel spasms, diarrhoea/constipation.	2002
36	ECHINACEA	BECLOMETHASONE, SALBUTAMOL	Urticaria (Recovered/resolved)	Severe urticarial rash with some purpura. The reporter did not consider the reaction to be serious.	2002
37	ECHINACEA, WARFARIN (Atrial fibrillation)		Haematuria (Recovering/resolving), International normalised ratio increased (Recovering/resolving)	The patient experienced an International Normalised Ratio (INR) level of 17.5. No other changes to medication in long term - stable anticoagulant patient had haematuria. Patient required admission and vitamin K. The reporter considered the reaction to be serious for the following reason: Life-threatening and medically significant: raised INR precipitate cerebral bleeding.	2003
38	ALLIUM SATIVUM (Prophylaxis), ECHINACEA (Prophylaxis), WARFARIN (Coronary artery bypass)	COD LIVER OIL, FRUSEMIDE AND TRIAMTERENE, LOSARTAN	Potentiating drug interaction (Not recovered/not resolved)	Dose of warfarin needed reducing to 5-10 mg once daily. Not considered harmful. Dose of Warfarin needed. Reducing to 5-6mg once daily. Not considered harmful. Patient has regular blood tests so reporter does not see any reason to discontinue the supplement. Patient taking garlic and echinacea during the winter for prophylaxis of colds and chest infections. It seems to have helped but patient's warfarin dose has had to be reduced regularly. Doctor suspects the garlic rather than echinacea.	1998

39	ECHINACEA	OXAZEPAM	Amnesia (Recovered/resolved), Ataxia (Recovered/resolved), Confusional state (Recovered/resolved), Dysarthria (Recovered/resolved), Hyponatraemia (Recovered/resolved), Osmotic demyelination syndrome (Recovered/resolved)	Hyponatraemia. Magnetic resonance imaging (MRI) scan showed central positive myelinolysis. Gradual recovery of slurred speech and ataxia, improved markedly with correction of sodium levels (by saline infusion). Since then patient has had two further episodes of acute confusion/memory loss but with normal sodium levels. Gingleo/Echinacea taken as a herbal remedy for 'general well being.' On further follow up by the neurologist patient now diagnosed as "transient epileptic amnesia" and is taking phenytoin for this.	1999
40	ECHINACEA (Nasopharyngitis)		Blood pressure increased (Recovered/resolved)	Increased blood pressure - (170/106, 150/105, 140/88 - stable for years). Returned to normal blood pressure of 148/88. Suspected drug - Holland & Barrett Echinacea. On no other drugs. No relevant history.	2000
41	ECHINACEA	ASPIRIN	Flushing (Recovering/resolving), Nausea (Recovering/resolving), Sleep disorder (Recovering/resolving)	Started to feel nauseated (no vomiting), and later that day felt very weak and felt a flush spreading from stomach upwards. Began to feel settled by the evening, but did not sleep well that night but was on the mend by the morning. Reaction to contraceptive pill. Completely disorientated and had to stop 30 years ago, and no other reactions since. The reporter did not consider the reaction to be serious	2002
42	ECHINACEA	COD LIVER OIL	Pollakiuria (Recovering/resolving)	Increase in urinary frequency. Patient had feeling that he was going into urinary retention. The reporter considered the reaction to be serious for the following reason: patient had feeling that was going into urinary retention. Patient referred for impaired glycaemia.	2000
43	ECHINACEA	CARBAMAZEPINE, OMEPRAZOLE	Arthralgia (Recovered/resolved), Fatigue (Recovered/resolved), Malaise (Recovered/resolved), Myalgia (Recovered/resolved), Rash (Recovered/resolved)	Bow-shaped rash across bridge of nose, temples and cheeks. Generalised pain in joints and muscles, malaise and tiredness. Stopped when medication stopped. Symptoms restarted when started therapy again. The patient's daughter has Systemic lupus erythematosus (SLE) and patient says that symptoms were lupus like symptoms. The reporter considered the reaction to be serious for the following reason - disability and incapacity. Follow up: Patient contacted Lupus society who state that they have received similar reports. Indication: ECHINACEA :Prophylaxis of colds	2001
44	ALLIUM SATIVUM, ECHINACEA	ATENOLOL, BENDROFLUAZIDE, DICLOFENAC	Burning sensation (Recovering/resolving), Erythema (Recovering/resolving), Oropharyngeal pain (Recovering/resolving)	Sore red throat. Red patch on left hand side of neck from ear to front of neck. Whole area burning and sore. Suspect drug: Beecham's echinacea and garlic batch number 24269A. The reporter did not consider the reaction to be serious.	2001
45	ECHINACEA		Flushing (Recovered/resolved), Palpitations (Recovered/resolved)		2007
46	ECHINACEA (Prophylaxis)		Rash (Unknown)		2010
47	ECHINACEA	HRT	Feeling abnormal (Recovered/resolved), Insomnia (Recovered/resolved), Palpitations (Recovered/resolved), Panic reaction (Recovered/resolved)	Panicky feelings, "fuzzy" feeling. Suspect drug - Potters Elixir of Echinacea; indication - to boost immune system. Other drug: HRT brand unknown.	2000

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