

FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022

All direct UK spontaneous suspected ADR reports received between 1st January 2012 up to and including 3rd October 2022 in association with all ferrous fumarate containing products, broken-down by the year and severity. Any ADR reports in which the form of the ferrous fumarate containing product was specified as oral solution, oral suspension or syrup have been excluded.

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022

Data Lock Date: 09-Oct-2022 18:30:04

Earliest Reaction Date: 01-Jul-2013

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	1	0
Blood disorders SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022

Data Lock Date: 09-Oct-2022 18:30:04

Earliest Reaction Date: 01-Jul-2013

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	6	0
<i>Rate and rhythm disorders NEC</i>		
Extrasystoles	1	0
Tachycardia	1	0
Cardiac disorders SOC TOTAL	8	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022

Data Lock Date: 09-Oct-2022 18:30:04

Earliest Reaction Date: 01-Jul-2013

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Ear disorders		
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
Ear disorders SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
 Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Eye disorders		
<i>Ocular disorders NEC</i>		
Eye pain	1	0
Eye swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	1	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal vein occlusion	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	1	0
Eye disorders SOC TOTAL	7	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Anal and rectal disorders NEC</i>		
Anal fissure	1	0
<i>Anal and rectal signs and symptoms</i>		
Anorectal discomfort	1	0
<i>Dental surface disorders</i>		
Tooth discolouration	4	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	36	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	6	0
Eructation	2	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
Faeces discoloured	15	0
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	5	0
Flatulence	3	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	18	0
Abdominal pain lower	1	0
Abdominal pain upper	22	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	25	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Dyschezia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	12	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	4	0
<i>Nausea and vomiting symptoms</i>		
Nausea	29	0
Vomiting	20	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	3	0
Melaena	1	0
Upper gastrointestinal haemorrhage	1	0
<i>Oesophageal ulcers and perforation</i>		
Oesophageal ulcer	1	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
Lip dry	1	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	1	0
<i>Oral soft tissue signs and symptoms</i>		

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
 Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Hypoaesthesia oral	1	0
Oral discomfort	1	0
Paraesthesia oral	1	0
Oral soft tissue swelling and oedema		
Lip swelling	6	0
Stomatitis and ulceration		
Mouth ulceration	1	0
Tongue signs and symptoms		
Swollen tongue	1	0
Tongue discolouration	1	0
Gastrointestinal disorders SOC TOTAL	232	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
 Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	2	0
Fatigue	10	0
Malaise	10	0
<i>Death and sudden death</i>		
Sudden death	1	1
<i>Feelings and sensations NEC</i>		
Feeling abnormal	4	0
Feeling hot	1	0
Hunger	1	0
<i>General signs and symptoms NEC</i>		
Illness	4	0
Peripheral swelling	1	0
Swelling face	3	0
Symptom masked	1	0
<i>Inflammations</i>		
Inflammation	1	0
<i>Interactions</i>		
Drug interaction	5	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	1	0
Chest pain	3	0
Discomfort	1	0
Facial pain	1	0
Pain	4	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	3	0
Drug intolerance	1	0
Therapeutic response unexpected	1	0
<i>Withdrawal and rebound effects</i>		
Withdrawal syndrome	1	0
General disorders SOC TOTAL	60	1

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	1	0
<i>Cholestasis and jaundice</i>		
Cholestasis	1	0
Ocular icterus	1	0
Hepatic disorders SOC TOTAL	4	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	4	0
Anaphylactic shock	1	0
Immune system disorders SOC TOTAL	8	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Pustule	1	0
Infections SOC TOTAL	3	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
 Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Foetal exposure during pregnancy	1	0
Maternal exposure during delivery	1	0
Maternal exposure during pregnancy	4	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	2	0
<i>Overdoses NEC</i>		
Overdose	2	0
<i>Product dispensing errors and issues</i>		
Product dispensing error	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
Skin injury	1	0
Skin wound	1	0
Injuries SOC TOTAL	14	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022

Data Lock Date: 09-Oct-2022 18:30:04

Earliest Reaction Date: 01-Jul-2013

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations		
<i>Heart rate and pulse investigations</i>		
Heart rate irregular	1	0
<i>Hepatobiliary function diagnostic procedures</i>		
Liver function test increased	1	0
Total bile acids increased	1	0
<i>Physical examination procedures and organ system status</i>		
Weight increased	2	0
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level increased	1	0
Investigations SOC TOTAL	6	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
 Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	5	0
Increased appetite	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	10	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
 Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Bone related signs and symptoms</i>		
Pain in jaw	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	2	0
Joint stiffness	1	0
<i>Muscle pains</i>		
Myalgia	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	1	0
Musculoskeletal stiffness	2	0
Posture abnormal	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	3	0
Pain in extremity	1	0
Muscle & tissue disorders SOC TOTAL	15	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
 Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Poor sucking reflex	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Ischaemic stroke	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	2	0
Dysstasia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	1	0
Loss of consciousness	1	0
Somnolence	2	0
<i>Dyskinesias and movement disorders NEC</i>		
Fine motor skill dysfunction	1	0
<i>Headaches NEC</i>		
Headache	13	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	1	0
<i>Migraine headaches</i>		
Migraine	2	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	8	0
Dizziness postural	1	0
Presyncope	1	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	1	0
<i>Paraesthesias and dysaesthesias</i>		
Paraesthesia	4	0
<i>Seizures and seizure disorders NEC</i>		
Seizure	2	0
<i>Sensory abnormalities NEC</i>		
Taste disorder	1	0
<i>Speech and language abnormalities</i>		
Speech disorder	1	0
<i>Tremor (excl congenital)</i>		
Tremor	2	0
Nervous system disorders SOC TOTAL	48	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022

Data Lock Date: 09-Oct-2022 18:30:04

Earliest Reaction Date: 01-Jul-2013

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Maternal complications of pregnancy NEC</i>		
Morning sickness	1	0
Pregnancy conditions SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022

Data Lock Date: 09-Oct-2022 18:30:04

Earliest Reaction Date: 01-Jul-2013

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
<i>Device physical property and chemical issues</i>		
Device colour issue	1	0
null SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
 Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Anxiety	2	0
<i>Behaviour and socialisation disturbances</i>		
Social avoidant behaviour	1	0
<i>Communications disorders</i>		
Communication disorder	1	0
<i>Depressive disorders</i>		
Depression	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	1	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	2	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	1	0
Psychiatric disorders SOC TOTAL	14	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Micturition disorder	1	0
<i>Urinary abnormalities</i>		
Urine odour abnormal	1	0
Renal & urinary disorders SOC TOTAL	3	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
 Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Nipple disorder	1	0
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	1	0
Menstruation irregular	1	0
<i>Menstruation with decreased bleeding</i>		
Menstruation delayed	1	0
Oligomenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	3	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	2	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal discomfort	1	0
Reproductive & breast disorders SOC TOTAL	12	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
 Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	7	0
Respiration abnormal	1	0
<i>Coughing and associated symptoms</i>		
Haemoptysis	1	0
Productive cough	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	3	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal discomfort	1	0
Rhinorrhoea	1	0
Sneezing	2	0
Respiratory disorders SOC TOTAL	17	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
 Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	1	0
<i>Alopecias</i>		
Alopecia	2	0
<i>Angioedemas</i>		
Angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	1	0
<i>Bullous conditions</i>		
Blister	1	0
Erythema multiforme	1	0
<i>Dermal and epidermal conditions NEC</i>		
Papule	1	0
Skin warm	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	3	0
Eczema	1	0
<i>Erythemas</i>		
Erythema	1	0
<i>Pilar disorders NEC</i>		
Hair colour changes	1	0
<i>Pruritus NEC</i>		
Pruritus	8	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	9	0
Rash erythematous	4	0
Rash pruritic	3	0
<i>Skin vasculitides</i>		
Vasculitic rash	1	0
<i>Urticarias</i>		
Urticaria	4	0
Skin disorders SOC TOTAL	46	0

Case Series Drug Analysis Print

Name: FOI 22/977 - Ferrous Fumarate Drug Analysis Print (DAP)

Report Run Date: 10-Oct-2022
 Earliest Reaction Date: 01-Jul-2013

Data Lock Date: 09-Oct-2022 18:30:04
 MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Vascular disorders		
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	1	0
<i>Non-site specific embolism and thrombosis</i>		
Venous thrombosis	1	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Hot flush	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
Vascular disorders SOC TOTAL	5	0
TOTAL REACTIONS FOR DRUG	516	1
TOTAL REPORTS	246	
TOTAL FATAL OUTCOME REPORTS		1