Unbranded Vitamin K Product Analysis Print

Report Run Date:	26-Apr-2023
Data Lock Date:	25-Apr-2023 18:30:04
Earliest Reaction Date:	21-Jun-1996
MedDRA Version:	MedDRA 25.1
Unbranded Vitamin K Product Analysis Print:	All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with parenteral Vitamin K (brand not reported) in which the patient was reported to be 1 years old or younger, or have a patient age group of neonate/infant.

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Cardiac disorders		
Rate and rhythm disorders NEC		
Bradycardia	1	0
Cardiac disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Congenital disorders		
Musculoskeletal and connective tissue disorders of limbs congenital		
Developmental hip dysplasia	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
Hearing losses		
Deafness bilateral	1	0
Ear disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Faecal abnormalities NEC		
Mucous stools	1	0
Non-site specific gastrointestinal haemorrhages		
Haematochezia	1	0
Gastrointestinal disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
General disorders		
Injection site reactions		
Injection site mass	1	0
Injection site swelling	1	0
Mass conditions NEC		
Cyst	1	0
Therapeutic and nontherapeutic responses		
Drug ineffective	1	0
Drug ineffective for unapproved indication	1	1
General disorders SOC TOTAL	5	1

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Reaction Name	Total	Fatal
Hepatic disorders		
Cholestasis and jaundice		
Jaundice	2	0
Hepatic disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Immune system disorders		
Allergies to foods, food additives, drugs and other chemicals		
Food allergy	2	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	1	0
Immune system disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Infections		
Herpes viral infections		
Eczema herpeticum	1	0
Infections SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Injuries		
Exposures associated with pregnancy, delivery and lactation		
Foetal exposure during pregnancy	2	0
Maternal exposure timing unspecified	1	0
Product administration errors and issues		
Wrong product administered	1	0
Injuries SOC TOTAL	**4**	**0**

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Reaction Name	Total	Fatal
Investigations		
Physical examination procedures and organ system status		
Respiratory rate decreased	1	0
Weight decreased	1	0
Investigations SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Metabolic disorders		
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Dairy intolerance	1	0
Gluten sensitivity	1	0
Milk soy protein intolerance	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	1	0
Metabolic disorders SOC TOTAL	**4**	**0**

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Reaction Name	Total	Fatal
Nervous system disorders		
Abnormal reflexes		
Poor sucking reflex	1	0
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebral haemorrhage	1	0
Haemorrhage intracranial	1	0
Disturbances in consciousness NEC		
Somnolence	1	0
Seizures and seizure disorders NEC		
Seizure	1	0
Nervous system disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
Neonatal hepatobiliary disorders		
Jaundice neonatal	1	0
Pregnancy conditions SOC TOTAL	**1**	**0**

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Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Hypopnoea	1	0
Respiratory disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Skin disorders		
Dermal and epidermal conditions NEC		
Skin plaque	1	0
Dermatitis and eczema		
Eczema	2	0
Pigmentation changes NEC		
Pigmentation disorder	1	0
Purpura and related conditions		
Petechiae	1	0
Rashes, eruptions and exanthems NEC		
Rash	1	0
Skin disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Vascular disorders		
Peripheral vascular disorders NEC		
Cyanosis	2	0
Site specific vascular disorders NEC		
Pallor	1	0
Vascular disorders SOC TOTAL	3	0
TOTAL REACTIONS FOR DRUG	42	1
TOTAL REPORTS	18	
TOTAL FATAL OUTCOME REPORTS		1