

Konakion Product Analysis Print

Report Run Date: 26-Apr-2023
Data Lock Date: 25-Apr-2023 18:30:04
Earliest Reaction Date: 21-Nov-1972
MedDRA Version: MedDRA 25.1

Konakion Product Analysis Print: All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with parenteral Konakion in which the patient was reported to be 1 years old or younger, or have a patient age group of neonate/infant.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Bleeding tendencies</i>		
Haemorrhagic disease of newborn	1	0
<i>Coagulopathies</i>		
Coagulopathy	3	0
<i>Haemolyses NEC</i>		
Haemolysis	1	0
Blood disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	2	0
Cardiac disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Anal incontinence	1	0
<i>Intestinal haemorrhages</i>		
Intestinal haemorrhage	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	1	0
Gastrointestinal disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
General disorders		
<i>Feelings and sensations NEC</i>		
Chills	1	0
<i>General signs and symptoms NEC</i>		
General physical health deterioration	1	0
Ill-defined disorder	1	0
<i>Injection site reactions</i>		
Injection site haematoma	1	0
Injection site mass	1	0
Injection site necrosis	3	0
Injection site reaction	5	0
<i>Pain and discomfort NEC</i>		
Pain	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Drug ineffective	2	0
General disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	6	0
Hepatic disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	6	0
Anaphylactoid reaction	4	0
Anaphylactoid shock	1	0
Immune system disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Cellulitis	1	0
<i>Infections NEC</i>		
Abscess	1	0
<i>Streptococcal infections</i>		
Streptococcal sepsis	1	0
Infections SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Injuries		
<i>Cerebral injuries NEC</i>		
Subdural haemorrhage	1	0
<i>Product administration errors and issues</i>		
Expired product administered	1	0
<i>Product preparation errors and issues</i>		
Product preparation issue	2	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
<i>Spinal fractures and dislocations</i>		
Spinal fracture	1	0
Injuries SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Investigations		
<i>Coagulation and bleeding analyses</i>		
International normalised ratio increased	1	0
<i>Hepatobiliary function diagnostic procedures</i>		
Blood bilirubin increased	1	0
Investigations SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin K deficiency	5	0
<i>Hypervitaminoses NEC</i>		
Hypervitaminosis	1	0
Metabolic disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	1	0
Cerebral infarction	1	0
Haemorrhage intracranial	1	0
Subarachnoid haemorrhage	1	0
<i>Disturbances in consciousness NEC</i>		
Somnolence	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	1	0
<i>Seizures and seizure disorders NEC</i>		
Seizure	1	0
<i>Tremor (excl congenital)</i>		
Tremor	2	0
Nervous system disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Neonatal disorders due to birth trauma (excl intracranial haemorrhages)</i>		
Perinatal brain damage	1	1
Pregnancy conditions SOC TOTAL	1	1

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	1	0
Respiratory arrest	1	0
<i>Bronchospasm and obstruction</i>		
Bronchospasm	2	0
<i>Coughing and associated symptoms</i>		
Haemoptysis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
Respiratory disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Angioedemas</i>		
Angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Hyperhidrosis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Pain of skin	1	0
Skin discolouration	1	0
Skin warm	1	0
<i>Erythemas</i>		
Erythema	1	0
<i>Purpura and related conditions</i>		
Petechiae	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	6	0
Rash erythematous	1	0
Rash macular	1	0
Rash maculo-papular	1	0
Rash pruritic	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
Skin disorders SOC TOTAL	18	0

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Vascular disorders		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	2	0
<i>Haemorrhages NEC</i>		
Haemorrhage	3	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	2	0
Flushing	2	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
Vascular disorders SOC TOTAL	10	0
TOTAL REACTIONS FOR DRUG	108	1
TOTAL REPORTS	57	
TOTAL FATAL OUTCOME REPORTS		1