NEONATAL Medication Monograph

PHYTOMENADIONE (Vitamin K)

This document should be read in conjunction with this **DISCLAIMER**

Unrestricted: Any prescriber may initiate treatment

Presentation	Ampoule: 2mg/0.2mL (Konakion MM Paediatric®) For IM, Oral, IV administration
Description	Fat soluble vitamin
Indications	Prevents and treats haemorrhagic disease of the newborn by promoting the synthesis of blood coagulation factors in the liver For neonatal biliary atresia and liver disease – Cholestasis **NOTE:** **Parent/Guardian consent is to be obtained prior to administration of Vitamin K.**
Contraindications	**Oral prophylaxis** is not recommended in infants who are premature, unwell, on antibiotics, have cholestasis or have diarrhoea - IM/IV Vitamin K must be administered **Oral prophylaxis** is contraindicated in infants of mothers who are taking rifampicin, vitamin K antagonists including warfarin or anticonvulsants including phenytoin, barbiturates and carbamazepine- IM/IV Vitamin K must be administered
Precautions	Severe hepatic dysfunction High dose IV administration is associated with a possible risk of kernicterus in premature infants Oral absorption may be impaired in short bowel syndrome, biliary atresia, and pancreatic insufficiency and malabsorption syndromes.
Dosage	**Prophylaxis of Vitamin K deficiency bleeding**: ***Do not prescribe unless the Vitamin K consent has been confirmed.*** **IM:** **Birth Weight ≤ 1500g:** 0.5 mg (0.05 mL) as a single dose **Birth Weight >1500g:** 1 mg (0.1 mL) as a single dose

<table>
<tr><td></td><td>
Oral:
A total of 3 doses must be administered when oral Vitamin K is used
<table>
<tr><th>Schedule</th><th>Days of Life</th><th>Dose</th></tr>
<tr><td>First Dose</td><td>At Birth</td><td>2 mg (0.2 mL)</td></tr>
<tr><td>Second Dose</td><td>Days 3-5</td><td>2 mg (0.2 mL)</td></tr>
<tr><td>Third Dose</td><td>Day 28</td><td>2 mg (0.2 mL)</td></tr>
</table>
IV:
Indicated for infants with birth weight ≤ 1000g:
0.5 mg (0.05 mL) as a single dose

<u>Cholestasis (neonatal biliary atresia or liver disease):</u>
<u>Oral:</u>
1 mg (0.1 mL) once a day
</td></tr>
<tr><td>Dosage Adjustment</td><td>Repeated doses are advised if infant vomits within an hour of an oral dose or if diarrhoea occurs within 24 hours of administration. Check with prescriber for further advice.</td></tr>
<tr><td rowspan="2">Adverse Reactions</td><td>Common: pain, swelling and erythema at IM injection site, flushing, cyanosis, rapid weak pulse, hypotension</td></tr>
<tr><td>Serious: hypersensitivity-like reaction (anaphylaxis and death has been reported with rapid IV administration), hyperbilirubinemia and kernicterus with excessive doses</td></tr>
<tr><td>Interactions</td><td>Co-administration of anticonvulsants can impair the action of vitamin K</td></tr>
<tr><td>Compatible Fluids</td><td>Glucose 5%, Glucose 10%, Sodium chloride 0.9%</td></tr>
<tr><td>Preparation</td><td>IV: May be diluted to 0.5mL if required for ease of administration</td></tr>
<tr><td>Storage</td><td>Store at room temperature, below 25°C
Protect from light- solution should be clear</td></tr>
</table>

Administration	***Do not administer unless consent has been confirmed.***
	Intramuscular: (Preferred route of administration) Administer undiluted.
	Oral: undiluted contents of ampoule may be given orally. Break ampoule, place dispenser vertically into ampoule, withdraw solution from ampoule into dispenser until solution reaches marking on dispenser (2 mg) and administer contents directly into mouth.
	Intravenous: Can be given via umbilical arterial or venous injection. Inject undiluted over at least 60 seconds (maximum 1mg per minute). Give slowly and only on recommendation of consultant.
Storage	Store at room temperature, below 25°C Protect from light - solution should be clear
Notes	Efficacy of treatment is decreased in patients with liver disease. Oral and IV doses may be less effective than a single IM dose for long-term prophylaxis of haemorrhagic disease of the newborn Near term or term infants with an intravenous line in situ should be administered Vitamin K IM due to the increased clearance of Vitamin K when given intravenously
Related clinical guidelines	Vitamin K Administration- Neonate
References	Society of Hospital Pharmacists of Australia. Phytomenadione. In: Australian Injectable Drugs Handbook [Internet]. [St Leonards, New South Wales]: Health Communication Network; 2019 [cited 2020 July 06]. Available from: http://aidh.hcn.com.au Royal Pharmaceutical Society. Phytomenadione in: BNF for Children [internet] 2019 [cited 2019 May 20]. Available from: https://www-medicinescomplete-com.smhslibresources.health.wa.gov.au/#/content/bnfc/PHP107738 Lilley L, Legge D. Paediatric injectable guidelines. 5th ed. Melbourne (Victoria): The Royal Children's Hospital; 2016. 90 South Australian Neonatal Medication Guidelines: Vitamin K injection guideline [internet] 2018 [accessed 2019 May 15]. Available from: SA Health Neonatal Medication Guidelines (SA) Auckland District Health Board Newborn Drug Protocols. Phytomenadione [internet] 2007 [accessed 2019 May 15]. Available from: http://www.adhb.govt.nz/newborn/DrugProtocols/ Truven Health Analytics. Phytomenadione. In: NeoFax [Internet]. Greenwood Village (CO): Truven Health Analytics; 2019 [cited 2019 July 26]. Available from: https://neofax.micromedexsolutions.com/ Williams MD, Chalmers EA, Gibson BE, Haemostasis, Thrombosis Task Force BCfSiH. The investigation and management of neonatal haemostasis and thrombosis. British Journal of Haematology. 2002;119:295-309. [cited 2020 July 07] https://onlinelibrary.wiley.com/doi/epdf/10.1046/j.1365-2141.2002.03674.x Loughnan, Pm, and Pn McDOUGALL. Does Intramuscular Vitamin K 1 Act as an Unintended Depot Preparation? *Journal of Paediatrics and Child Health* 32.3 (1996): 251-54. [Cited 2020 July]

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