

This information was up to date at the time of release to the Heads of Midwifery.

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Updating arrangements for the formulary should be decided upon and implemented at a local level.

Phytomenadione (Vitamin K) Oral (NeoKay®) Neonate	
Legal status (GSL, P or POM on exemption list, or PGD)	<ul style="list-style-type: none"> ▪ POM - midwife may administer as medicine is on midwives exemptions list
Patient group	Healthy neonates, including healthy preterm babies.
Clinical indication	For prophylaxis of vitamin K deficiency bleeding (VKDB).
Pharmacology (Onset and duration of action where appropriate)	Vitamin K is needed for the blood clotting process and deficiency can increase the risk of VKDB. It is essential for the formation clotting factors VII, IX, and X, and prothrombin in the liver and of the coagulation inhibitors, protein C and protein S.
Pharmaceutical form, strength, route of administration	Capsule contains 1mg phytomenadione. For oral administration.
Dose, frequency and maximum number of doses or period of time for administration or supply	<p>Oral prophylaxis in healthy neonates, including healthy preterm babies:</p> <p>The contents of a single Neokay capsule should be administered by cutting the narrow tubular tip off the capsule and squeezing the liquid into the baby's mouth. Another dose should be given if the first dose is spat out or the baby is sick within three hours of the dose being given.</p> <p>Exclusively breast fed babies:</p> <p>The administration of 1mg Neokay by mouth at birth protects healthy term babies from the risk of bleeding due to vitamin K deficiency in the first week of life. Evidence to date suggests that for babies who are being exclusively breast-fed, a dose of 1mg once weekly for 12 weeks offers the best protection against late vitamin K deficiency bleeding.</p>
Contra-indications/exclusion criteria	<ul style="list-style-type: none"> ▪ neonates of mothers taking carbamazepine, phenobarbital, phenytoin, rifampicin or warfarin at the time of delivery ▪ neonate is unwell and is likely to be transferred to neonatal unit ▪ babies who are not well enough to be fed within a few hours of birth ▪ known hypersensitivity to any constituents or where there are objections to use of product containing gelatin of bovine origin ▪ if contra- indicated should be treated with an intramuscular formulation of vitamin K at birth ▪ refer to paediatrician

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Cautions and action that will be taken if a caution applies	<ul style="list-style-type: none"> ▪ infants with cholestatic disease must receive IM or IV since oral absorption is impaired ▪ take expert advice before giving NeoKay to any baby with protein C or protein S deficiency currently on treatment with warfarin ▪ check for and document any allergies ▪ check and document past medical and drug history and current medication to ascertain potential for overdose ▪ if a caution applies consult with a doctor ▪ document consultation in maternity record
Medicine interactions and action that will be taken if a patient is taking a medicine that may interact	<ul style="list-style-type: none"> ▪ none relevant ▪ if there is a clinically significant drug interaction, consult with a doctor before administration or supply ▪ document consultation in maternity record ▪ refer to current BNF for latest information on interactions
Potential adverse reactions and side effects including actions to be taken if adverse medicine reaction is suspected	<ul style="list-style-type: none"> ▪ no adverse effects have been associated with oral administration ▪ <i>if a serious adverse reaction is suspected please report to the MHRA Yellow Card Scheme http://yellowcard.mhra.gov.uk/</i>
Overdose	<ul style="list-style-type: none"> ▪ no case of overdose has been reported ▪ immediate assessment/treatment is essential - refer to medical staff ▪ manage in accordance with established treatment guidelines or see BNF overdose section ▪ for further advice contact National Poisons Centre 0344 892 0111
Additional advice and	<ul style="list-style-type: none"> ▪ supply the manufacturer's patient information leaflet if requested
Patient monitoring arrangements during and after treatment and follow-up required	<p>Ensure there are arrangements for further doses.</p> <p>Refer to medical staff if parents object to prophylactic vitamin K by any route.</p> <p>The source of gelatine in Neokay capsules is of animal origin (cattle) which originate in different countries. BSE certificates are available on request.</p>
Particular storage requirements	<ul style="list-style-type: none"> ▪
References <ol style="list-style-type: none"> 1. Summary of product characteristics (Neokay®) Text revision 7.6.2017 http://www.medicines.org.uk Accessed 2.1.2020 2. http://bnfc.org 	