

MCN for Neonatology

West of Scotland

Neonatal Guideline



Vitamin K Prophylaxis for Neonates

Introduction

This document is applicable to all medical, midwifery and nursing staff caring for the newborn in hospital or community in the West of Scotland. The guideline should be used with reference to the relevant pharmacy monographs. Nursing staff should also refer to the Patient Group Direction (PGD) which covers the administration and supply of Konakion MM and NeoKay, by nursing and midwifery staff, for the prevention of Haemorrhagic Disease of the Newborn.

Intramuscular vitamin K – [Formulary Link](#)

The administration of an Intramuscular dose of Vitamin K (Konakion MM) is recommended for all babies born in the West of Scotland. It should be administered soon after birth. This is a ONCE ONLY dose. The dose is: -

- 1mg Konakion MM (0.1ml) IM for term infants (36 weeks gestation or greater).

A lower dose is recommended for infants < 36 weeks gestation. Two dosage regimes are in use in neonatal units in the West of Scotland. The former is the recommended dose in GG&C

- 0.5mg Konakion MM (0.05ml) IM for all preterm infants less than 36weeks.

OR

- 400 micrograms/kg (0.04 ml/kg) IM.

NB - A 1ml syringe must be used due to the very small volume for injection

If intramuscular injections are contraindicated (e.g. babies with inherited disorders of coagulation or babies with very low muscle mass) then vitamin K may be prescribed via the oral route or by intravenous injection if the enteral route is contraindicated or unreliable. See below.

Oral vitamin K

Note - The oral route is not appropriate for high risk, sick, or premature infants. In addition, the manufacturers do not recommend this route for babies born to mothers who are taking carbamazepine, phenobarbital, phenytoin, rifampicin or warfarin at the time of delivery. If a mother of a baby in any of these categories declines parenteral vitamin K or if a mother declines vitamin K by any route - see later section – *'Parents who decline vitamin K prophylaxis'*.

Mothers of healthy, mature, infants who decline intramuscular vitamin K should be offered one of the following oral Vitamin K regimens.

NeoKay 1mg capsules - 1mg orally, once weekly for 12 weeks – [Formulary Link](#)

Administration - 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. The preparation comes in packs of 12 capsules which is sufficient for a full course. Note that the capsule is made from Gelatin and although this is not ingested, this may be an issue for some vegan families.

Advice to Parents – The parents should be advised that all doses must be given to ensure adequate prophylaxis against both early and late onset haemorrhagic disease. NeoKay information leaflet attached to this document.

If NeoKay is unavailable then Konakion MM may be used according to the following schedule.

Konakion MM Paediatric – 2mg (0.2ml) orally, Three doses at 1, 7 and 28 days – [Formulary Link](#)

Administration – Konakion MM Paediatric is supplied in glass ampoules. Arrangements will need to be made to allow administration by health professionals. This would usually be the community midwife or the health visitor.

Intravenous vitamin K – [Formulary Link](#)

Konakion MM may be administered intravenously but this is not recommended for routine treatment. Intravenous administration is not covered by the PGD and must be prescribed by a doctor.

Konakion MM must only be diluted with 5% glucose & not mixed with other intravenous medications or infusions. The line should be flushed with IV glucose 5% before and after administration.

As intravenous administration does not provide a depot of vitamin K the manufacturers recommend administration of additional doses at 7 days and 4 weeks of age.

Patient Group Direction

The administration of Konakion MM (oral or IM) and NeoKay (orally) by midwives and nurses employed by Greater Glasgow & Clyde Health Board are covered by a Patient Group Directions (PGDs). The PGDs permit the administration of IM Konakion or oral NeoKay or Konakion MM on labour wards, the neonatal units and at home deliveries, without a medical prescription.

Informed consent for the administration of vitamin K.

Parents are asked to provide verbal consent for the administration of intramuscular vitamin K. Staff should be aware of the following key points when discussing vitamin K administration, to ensure that this consent is fully informed.

- Vitamin K is required for the production of essential clotting factors in the liver. Haemorrhagic disease of the newborn (HDN) is caused by a deficiency of vitamin K. HDN may cause severe bleeding which may be fatal or cause severe brain damage. Bleeding can occur without warning.
- Vitamin K 1mg (or 0.5mg for premature babies) intramuscularly gives universal protection against HDN ¹.
- Whilst some studies in the early 1990's suggested a link between IM vitamin K and childhood cancers, subsequent research has not confirmed these findings. Such a link is therefore deemed to be unproven and unlikely ². Therefore, the possibility of a link between IM vitamin K and childhood cancer should not be raised with parents when seeking consent for the administration of Vitamin K.
- It is the agreed policy therefore to give vitamin K intramuscularly. However, if some parents object to IM administration of vitamin K then the alternative offered is oral Vitamin K (see dosage & administration information above). This however does NOT guarantee full protection, particularly if some doses are vomited or missed. Babies with liver disease are at particular risk.

Listed below are some important factors.

- Breast milk contains LESS Vitamin K than formula milks and breast fed babies have a reduced intake in the first few days. As a result of this haemorrhagic disease of the newborn has the greatest incidence amongst breast fed babies. This is not a reason not to breast feed but a reason for Vitamin K prophylaxis.
- Vitamin K is a fat soluble Vitamin and is poorly absorbed from the gut when there is liver disease. Many liver diseases are not apparent for days or weeks after birth, therefore, these babies cannot be identified when prophylaxis is first given. Small, repeated doses of oral Vitamin K will reduce the risk. Midwives should be alert to the possibility of liver disease signified by prolonged jaundice after 14 days.
- Babies of mothers who are taking some enzyme-inducing drugs - carbamazepine, phenobarbital, phenytoin or rifampicin, or who are taking warfarin must have prophylactic Vitamin K given parenterally. These drugs antagonise Vitamin K in the baby.

Parents who decline vitamin K prophylaxis

Parents of healthy term babies have the right to refuse consent for vitamin K prophylaxis by any or all routes. However, we have a duty to explore the reasons for complete refusal and ensure that they are correctly informed of the risks of Vitamin K deficient bleeding and the potential for serious long term morbidity or mortality. If, having explored the reasons for refusal and having ensured that they are correctly informed of the risks, they continue to refuse prophylactic vitamin K then this conversation and their decision should be clearly documented in the baby notes. It is not appropriate to get the parents to sign a medical 'disclaimer'. This discussion should be with a Middle Grade or Consultant Paediatrician.

Where a baby is clearly at high risk of bleeding however, vitamin K is required as treatment rather than prophylaxis and should always be administered in the best interests of the baby.

Such cases would include:

- Prematurity
- Sepsis
- Liver disease
- Maternal treatment with enzyme inducing drugs including e.g. Anticonvulsants and Rifampicin
- Prolonged Prothrombin time

Information to be given to parents if vitamin K prophylaxis is declined

- Vitamin K is an essential vitamin required by the liver to make 'clotting factors'. Clotting factors are natural chemicals produced by the liver which circulate in the blood and respond to bleeding by helping blood clots to form.
- Babies who do not get enough vitamin K are at risk of bleeding excessively over the first few days and weeks of life. This is called vitamin K deficient bleeding (VKDB) or Haemorrhagic Disease of the Newborn (HDN).
- Bleeding most commonly occurs between day 2 and day 7 of life. This is known as 'Classical' VKDB. Classical VKDB is almost entirely preventable by giving the baby vitamin K. Bleeding may also occur later than this over the following few months. This is known as 'Late' VKDB. This may also be reduced by giving the baby Vitamin K although there is insufficient research to confirm this.
- Rarely, bleeding can occur on day 1 of life. This is called 'Early' VKDB.
- The excessive bleeding seen in VKDB may appear as severe or unexplained bruising, oozing of blood from the umbilical stump or from injection sites, nose bleeds or bleeding from the stomach or bowel. These types of bleeding serve as a warning that the baby's blood is not clotting but seldom cause severe illness.
- The main concern however, is bleeding within the brain which can occur without any warning and may lead to permanent brain damage or death.
- Breast milk, whilst being the healthiest way to feed your baby, contains very little vitamin K and the majority of bleeds reported in the UK occur in babies who have been fed exclusively with breast milk³. Most of the other bleeds were seen in babies fed with soya based formula milk or who are absorbing vitamin K poorly due to liver disease³.
- Severe bleeding can be almost completely prevented by giving Vitamin K at the time of birth by an intramuscular injection. And this is the reason that West of Scotland maternity units recommend this treatment for all babies. This recommendation is supported by all major health agencies⁸.
- Vitamin K given by mouth, according to the schedules above, is almost as effective as the intramuscular injection. However a number of babies each year are reported to have had bleeds

because some doses were missed or because the baby vomited shortly after the dose was given or because the Vitamin K did not get absorbed due to liver disease in the baby. Because of this we recommend intramuscular vitamin K as the safest option. However, if parents do not want the intramuscular injection then oral treatment can be offered.

- If no Vitamin K is given at birth the risk of spontaneous bleeding for all babies is around 1:8500⁴. The risk for exclusively breastfed babies is higher - around 1:1200⁶. Many more of these babies - up to 1:80, may show excess bleeding following minor surgical procedures such as circumcision⁷.
- Babies with specific risk factors including liver disease, prematurity or those born to mothers who are on medicines for epilepsy are at a much higher risk and treatment of these babies with Vitamin K is essential.

Resources for Families

Families can be directed to the leaflet attached to the end of this document

References

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2. American Academy of Pediatrics. Policy Statement - Controversies Concerning Vitamin K and the Newborn (RE9302). Vitamin K Ad Hoc Task Force. Pediatrics May 1993 91 (5), 1001-1003
3. McNinch A et al. Vitamin K deficiency bleeding in Great Britain and Ireland: British Paediatric Surveillance Unit Surveys, 1993-94 and 2001-02. Arch Dis Child 2007; 92;759-766
4. Busfield A et al. Neonatal Vitamin K prophylaxis in Great Britain and Ireland; The impact of perceived risk and product licensing on effectiveness Arch Dis Child 2007; 92; 754-75
5. Prophylactic vitamin K for vitamin K deficiency bleeding in neonates (Review) 27. Copyright © 2006 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd
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7. Sutherland JM et al. Haemorrhagic Disease of the Newborn: breastfeeding as a necessary factor in the pathogenesis 1967; 113:524-533
8. Jullien S. Vitamin K prophylaxis in newborns. BMC Pediatr. 2021 Sep 8;21(Suppl 1):350. doi: 10.1186/s12887-021-02701-4. PMID: 34496783; PMCID: PMC8424792.

Document Properties

Document Title

WoS_VitaminK_Neonates

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Acknowledgement of input to previous version

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Pharmacy - June Grant

Implementation and review dates

Implementation date 14/10/19 Reviewed 20/10/22 Next review 01/10/25

NeoKay 1mg Capsules

Phytomenadione

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or healthcare professional.
- If you notice any side effects not listed in this leaflet, please tell your doctor or healthcare professional.

In this leaflet:

1. What Neokay is and what it is used for
2. Before you use Neokay
3. How to use Neokay
4. Possible side effects
5. How to store Neokay
6. Further information

1. WHAT NEOKAY IS AND WHAT IT IS USED FOR

Neokay contains phytomenadione, a synthetic Vitamin K, which is essential in the body for blood to clot. Newborn babies can have too little Vitamin K and so may develop a serious, but rare condition that causes bleeding. Neokay is used to prevent your baby from developing a tendency to bleed due to a deficiency in vitamin K.

2. BEFORE YOU USE NEOKAY

Do not use Neokay:

- if your baby is showing any signs of an allergic reaction to Neokay or any of its ingredients (listed in section 6).
- if your baby is not well enough to be fed within a few hours of birth
- if the baby's mother is taking carbamazepine, phenobarbital, phenytoin, rifampicin or warfarin.

Take special care with Neokay:

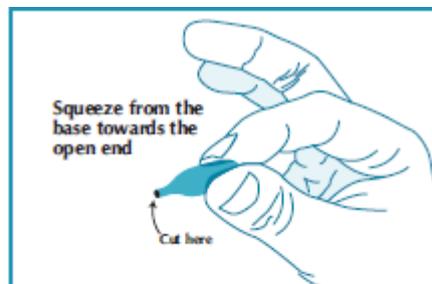
- if your baby has protein C or protein S deficiency and/or is currently taking warfarin. Do not give Neokay to your baby unless specifically advised to do so by their consultant.
- If your baby has a bleed (eg from the cord stump) or shows signs of bruising consult your doctor immediately.

3. HOW TO USE NEOKAY

Always use Neokay exactly as your doctor has told you. You should check with your doctor or healthcare professional if you are not sure.

Healthy newborn babies, including healthy premature babies:

The contents of a single Neokay capsule should be given. Cut the narrow tip off the capsule and squeezing the liquid into the baby's mouth, as shown in the picture. 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.



Breast-fed babies:

Breast milk contains relatively little vitamin K. The contents of a single Neokay capsule should be given at birth. This protects healthy babies from the risk of bleeding due to vitamin K deficiency in the first week of life. For babies who are only being breast-fed, the contents of a single capsule should be given once weekly for 12 weeks. This offers the best protection against late vitamin K deficiency bleeding. Each dose should be given as described above.

If you forget to give a dose, give one as soon as you remember and continue to give the remainder of the doses as directed.

If you have any further questions on the use of this product, ask your doctor or healthcare professional.

4. POSSIBLE SIDE EFFECTS

There are no known side effects from taking Neokay. If you do notice any side effects, please tell your doctor or healthcare professional.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NEOKAY

Do not store above 25°C. Do not freeze. Store in the original package.

Keep out of the sight and reach of children.

Do not use Neokay after the expiry date which is stated on the bottle (EXP). The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your healthcare professional how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION**What Neokay contains**

- Each capsule contains 1mg of the active substance phytomenadione
- The other ingredient is fractionated coconut oil

What Neokay looks like and contents of the pack

Neokay comes as a dark brown soft capsule containing a clear, odourless pale yellow liquid. It is packed in polypropylene plastic bottles with caps made from a blend of low and high density polyethylene. It is available in pack sizes of 12 or 100 soft gelatin capsules.

Marketing Authorisation Holder

Neoceuticals Limited, The Innovation Centre, Innovation way, Heslington, York, YO10 5DG

Manufacturer

Central Pharma (Contract Packing) Ltd, Caxton Road, Bedford, MK41 0XZ

This leaflet was last approved in 10/2018.

NCLF01-6

Vitamin K for Newborn Babies

Information for parents

This leaflet explains what vitamin K is, and its importance in preventing bleeding problems in newborn babies. We hope it gives you enough information to help you make an informed choice about this part of your baby's care.

What is vitamin K?

Vitamin K occurs naturally in food (especially red meat and some green vegetables). It is also produced by friendly bacteria in our gut. We all need it as it helps to make our blood clot and to prevent bleeding problems. Newborn babies and young infants have very little vitamin K.

How do low levels of Vitamin K affect a newborn baby?

A very small number of babies suffer bleeding problems due to a shortage of vitamin K.

This is called Vitamin K Deficiency Bleeding (or VKDB for short). The classical form usually happens in the first week of life. The baby may bleed from the mouth or nose or from the stump of the umbilical cord.

Late onset VKDB is a more serious problem which happens after the baby is about three weeks old. The bleeding is sometimes into the gut or the brain and in some cases it can cause brain damage or even death.

How can Vitamin K Deficient Bleeding be prevented?

The Scottish Government recommends that all newborn babies are given vitamin K to reduce the chances of dangerous internal bleeding. The most effective treatment is a single dose of vitamin K injected into the thigh muscle shortly after birth. Vitamin K by mouth is also effective in most cases but your baby will need to have a number of doses through the first 1-3 months of life. Vitamin K by mouth may not work in a small number of babies.

Does my baby get vitamin K from their milk?

Whilst breastfeeding is recommended due to its many benefits for baby and mother, it contains very little vitamin K, and therefore breast feeding does not prevent VKDB. Most cases of VKDB in the UK occur in breastfed babies who have not any vitamin K supplements or in babies who have not completed a full course of vitamin K given by mouth (if some doses are missed or vomited)¹.

Formula milk has vitamin K added (except Soya Formula) but some formula fed babies, who have not had an injection of vitamin K, do get VKDB if they have problems with their liver¹. Babies with liver disease do not absorb vitamin K very well from their milk.

When do I need to start thinking about this?

During your pregnancy you must consider whether your baby should receive vitamin K, and if so, how it should be given. Vitamin K for your baby should be given as soon as possible after birth.

What is the risk?

VKDB occurs in one in every 8,500 full term babies if no vitamin K supplement is given. In the whole of the UK, if no vitamin K supplement was given, 10 to 20 of the 800,000 babies born each

year might be brain damaged as a result of a bleed into the brain, and about five babies would die of this condition.

Final thoughts

If you decide against vitamin K supplements for your baby it is extremely important to be aware of the risk of VKDB. **Remember that in most cases there are no warning signs.**

You should seek medical help at once if there is any of the following

- Easy bruising especially around the baby's head and face.
- Bleeding from the nose or umbilical cord
- Jaundice (yellow eyes and skin) after the first 3 weeks
- Blood in the stool, black tarry stool or vomiting blood
- Paler than usual skin colour
- Irritability, seizures, excessive sleepiness, or repeated vomiting

This leaflet has been written to help you understand the importance of giving your baby vitamin K, but do not be alarmed. VKDB is uncommon and, although serious, the condition is preventable.

Further information

¹McNinch A, Busfield A, Tripp J Vitamin K deficiency bleeding in Great Britain and Ireland: British Paediatric Surveillance Unit Surveys, 1993–94 and 2001–02 Archives of Disease in Childhood 2007;92:759-766.