This information was up to date at the time of release to the Heads of Midwifery.
The editorial board does not accept liability for any errors or omissions following its subsequent publication.
Updating arrangements for the formulary should be decided upon and implemented at a local level.

Phytomenadione (Vitamin K) Intramuscular Neonate

Legal status (GSL, P or POM on exemption list, or PGD)	▪ POM - midwife may administer as medicine is on midwives exemptions list
Patient group	Healthy neonates of 36 weeks gestation and older.
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 Vitamin K Deficiency Bleeding (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. A single 1mg IM dose gives similar vitamin K_1 concentrations at 1 month as two oral doses of 2 mg doses, one at birth and another at one week.
Pharmaceutical form, strength, route of administration	Ampoule contains 2mg phytomenadione in 0.2ml in a mixed micelles vehicle of glycocholic acid and lecithin. For intramuscular injection.
Dose, frequency and maximum number of doses or period of time for administration or supply	1mg (0.1ml) Single dose at birth. NB ampoule contains 2mg in 0.2ml.
Contra-indications/exclusion criteria	▪ known hypersensitivity to any constituents; glycocholic acid, lecithin, sodium hydroxide and hydrochloric acid ▪ neonate < 36 weeks gestation or < 2.5kg. See local guidelines. ▪ neonate is unwell and is likely to be transferred to neonatal unit ▪ neonate where intramuscular route of administration is contra-indicated. ▪ refer to paediatrician
Cautions and action that will be taken if a caution applies	▪ infants with cholestatic disease must receive IM or IV since oral absorption is impaired ▪ following incorrect storage, the contents may become turbid or present a phase-separation - in this case the ampoule must not be used ▪ 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

Phytomenadione (Vitamin K) Intramuscular Neonate

Medicine interactions and action that will be taken if a patient is taking a medicine that may interact	▪ 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	▪ *parenteral administration to premature babies weighing less than 2.5kg may increase the risk for the development of kernicterus (bilirubin encephalopathy)* ▪ *hypersensitivity reactions are rare with only a few unconfirmed reports of anaphylactoid reaction after IV administration.* ▪ *pain, swelling and tenderness and very rarely atrophy and necrosis at injection site* ▪ *if a serious adverse reaction is suspected please report to the MHRA Yellow Card Scheme http://yellowcard.mhra.gov.uk/*
Overdose	▪ no known syndrome of hypervitaminosis of vitamin K ▪ possible reaction to overdose are jaundice, hyperbilirubinaemia, increase GOT and GGT, abdominal pain, constipation, soft stools, malaise, agitation and cutaneous eruption ▪ 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 information	▪ give the manufacturer's patient information leaflet to the parents if requested
Patient monitoring arrangements during and after treatment and follow-up required	Parents who do not wish their child to have an IM dose should be offered oral treatment. See phytomenadione oral monograph. Refer to medical staff if parents object to prophylactic vitamin K by any route.
Particular storage requirements	▪ following incorrect storage, the contents may become turbid or present a phase-separation and the ampoule must not be used

References

1. Summary of Product Characteristics (Konakion MM Paediatric®) Text revision 3.4.2019 http://www.medicines.org.uk Accessed 2.1.2020
2. http://www.bnfc.org