ST LUKE'S, SIR PAUL BOFFA, MATER DEI
HOSPITALS

DRUGS AND THERAPEUTICS COMMITTEE

Prof. Carmel Mallia MD, FRCP(Edin), FRCP(Lond), FCPP
Chairman

17 October 2006

Attention all Medical Practitioners
Nurses & Midwives
Pharmacists

Re : Discontinuation of Konakion® Neonatal 2mg/mL in 0.5-mL ampoules and replacement by Konakion® MM Paediatric 10mg/mL in 0.2-mL ampoules

Please note that the currently available phytomenadione (Vitamin K_1) parenteral paediatric preparation - Konakion® Neonatal 2mg/mL in 0.5-mL ampoules - is being discontinued by the manufacturer and will be replaced by Konakion® MM Paediatric 10mg/mL in 0.2-mL ampoules.

Phytomenadione (Vitamin K_1) is the active ingredient of Konakion® and is a procoagulant factor. As a component of the hepatic carboxylase system, vitamin K_1 is involved in the post-transitional carboxylation of clotting factor II (prothrombin), VII, IX and X and the clotting inhibitors protein C and protein S.

Change in volume
Please note that since the Konakion® Neonatal preparation varies in concentration from Konakion® MM Paediatric, there will be a change in the volume of injection that is administered. A 1mg dose of Konakion® MM Paediatric will require administration of a 0.1mL volume *(approximately half of the ampoule volume)*. This compares to an injection volume of 0.5mL for the previous recommended 1mg dose of Konakion® Neonatal ampoules *(nearly all of the ampoule volume)*.

Particular care is therefore required when administering a 1mg dose of Konakion® MM Paediatric, **not** to draw up and inject the entire contents of the ampoule, as this would result in approximately twice the recommended dose being given. The remaining volume in the ampoule is to be discarded.

Intramuscular administration
Konakion® MM Paediatric is licensed amongst other indications for the prophylaxis of Vitamin K_1 deficiency bleeding in neonates. *This preparation may be administered by mouth, or by intramuscular injection, or by intravenous injections*. However as discussed with the Department of Paediatrics, Konakion® MM Paediatric will **only** be administered **intramuscularly,** for the routine prophylaxis administration of Vitamin K_1 to all neonates at birth. This will simplify administration and minimize the risk of medication error.

According to the Summary of Product Characteristics (SPC) for Konakion® MM Paediatric, the dosage regimens for intramuscular administration, for the above indication are as follows:

(i) *Healthy neonates of 36 weeks gestation and older* : 1mg administered by intramuscular injection at birth or soon after birth,

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(i) *Preterm neonates of less than 36 weeks gestation weighing 2.5kg or greater, and term neonates at special risk* : 1mg intramuscularly at birth or soon after birth, the size and frequency of further doses depending on coagulation status,

(ii) *Preterm neonates of less than 36 weeks gestation weighing less than 2.5 kg* : 0.4mg/kg (equivalent to 0.04mL/kg) intramuscularly at birth or soon after birth. This parenteral dose should not be exceeded. The frequency of further doses should depend on coagulation status. CAUTION : care is required when calculating and measuring the dose in relation to the baby's weight (10 fold errors are common).

Use of special syringes

Konakion® MM Paediatric must **not be diluted** before injection, as incompatibilities have been observed with the diluted preparation and certain siliconised syringes.

For the administration of injection volumes of 0.04mL to 0.1mL of undiluted Konakion® MM Paediatric, **0.5mL syringes** with 0.01mL graduations supplied by **B.Braun,** will be provided.

Further to the above kindly note that Konakion® MM Paediatric can be administered for other indications, by using different routes of administration. In this case more information may be obtained from the SPC of the product or the Medicines and Poisons Information Section IPD/SLH (Tel no. 2595 2057).

Please note that stocks of Konakion® MM Paediatric will only be available once all the current supply of Konakion® Neonatal has been used up.

For your attention please,

Prof Carmel Mallia
Chairman
Drugs and Therapeutics Committee