SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

KONAKION® MM PAEDIATRIC Ampoule

Phytomenadione (Vitamin K_1)

Read all of this leaflet carefully before you receive KONAKION MM PAEDIATRIC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- KONAKION MM PAEDIATRIC has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

1. WHAT KONAKION MM PAEDIATRIC CONTAINS

Each KONAKION MM PAEDIATRIC ampoule contains 2 mg vitamin K_1 (phytomenadione) in 0,2 mℓ.

The other ingredients are glycocholic acid, sodium hydroxide, lecithin, hydrochloric acid and water for injection.

2. WHAT KONAKION MM PAEDIATRIC IS USED FOR

KONAKION MM PAEDIATRIC is used for prevention and treatment of bleeding due to deficiency of vitamin K in the newborn.

KONAKION MM PAEDIATRIC is used for babies who do not have enough vitamin K in their bodies. Giving KONAKION MM PAEDIATRIC prevents and treats bleeding caused by a lack of vitamin K.

KONAKION MM PAEDIATRIC works by helping your body make blood clotting factors. These blood clotting factors help stop bleeding.

3. BEFORE YOUR BABY IS GIVEN KONAKION MM PAEDIATRIC

Your baby must not be given KONAKION MM PAEDIATRIC if they are allergic (hypersensitive) to:

Phytomenadione or any of the other ingredients of KONAKION MM PAEDIATRIC.

If you are not sure if this applies to your baby, talk to your doctor, nurse, midwife or pharmacist before they are given KONAKION MM PAEDIATRIC.

Taking other medicines

Please tell your doctor, nurse or midwife if your baby is taking or has recently taken any other medicines. This includes medicines that you buy without a prescription, complementary or traditional medicines. This is because KONAKION MM PAEDIATRIC can affect the way some medicines work. Also some other medicines may affect the way KONAKION MM PAEDIATRIC works.

In particular, tell your doctor, nurse, midwife or pharmacist if your baby is taking medicines to stop their blood clotting (anticoagulants).

If any of the above apply to your baby, or if you are not sure, talk to your doctor, nurse, midwife or pharmacist before your baby is given KONAKION MM PAEDIATRIC.

4. HOW KONAKION MM PAEDIATRIC IS GIVEN

KONAKION MM PAEDIATRIC can be given to your baby by injection into a vein or muscle, or by mouth (orally). How it is given will depend upon what the medicine is being used for and whether your baby was born prematurely. The doctor will decide how much KONAKION MM PAEDIATRIC your baby needs.

If you have the impression that the effect of KONAKION MM PAEDIATRIC is too strong or too weak, talk to your doctor or pharmacist.

How to give your baby KONAKION MM PAEDIATRIC by mouth:

If your baby was given KONAKION MM PAEDIATRIC by mouth at birth, you will be asked to give your baby another 2 mg dose. You will give this by mouth 4 to 7 days after birth.

If your baby is having breast milk and no formula milk, you may be asked to give your baby a further 2 mg dose (by mouth) after 4 – 6 weeks.

- Shake the ampoule until the liquid is in the bottom of the ampoule. Do not use it if it looks cloudy.
- Hold the bottom part of the ampoule between the thumb and first finger of one hand. Make sure the spot is facing **towards** your thumb.
- Hold the top of the ampoule between the thumb and first finger of your other hand. Snap the top off by pushing **away** from the side with the spot.
- Place the dispenser vertically into the ampoule. Withdraw the solution from the ampoule into the dispenser until the solution reaches the marking of the dispenser (= 2 mg vitamin K_1).

- There may be some liquid left over in the ampoule even after the right dose has been removed. This is OK. Do not give your baby any extra liquid.
- Place the dispenser into your baby's mouth and gently give your baby the medicine.
- If no dispenser is available, you can use a syringe (without the needle), instead.

If your baby gets more KONAKION MM PAEDIATRIC than they should

If your baby has had more KONAKION MM PAEDIATRIC than they should, you must talk to a doctor, nurse, midwife or pharmacist.

The following effects may happen to your baby; jaundice (signs of which are yellowing of the skin or the whites of the eyes), tummy ache, constipation, soft stools (poo), seeming unwell, being agitated (upset), a rash and changes to how well their liver works (shown up by blood tests).

If you forget to give your baby KONAKION MM PAEDIATRIC

- If you forget to give your baby their dose of KONAKION MM PAEDIATRIC by mouth, talk to your doctor, midwife or pharmacist about when to give the next dose.
- Do not give your baby a double dose to make up for a forgotten dose.

If someone else takes your baby's KONAKION MM PAEDIATRIC by mistake, they should talk to a doctor or go to a hospital straight away.

Do not share KONAKION MM PAEDIATRIC prescribed for your baby with another person.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

5. POSSIBLE SIDE-EFFECTS

KONAKION MM PAEDIATRIC can have side effects.

Stop giving KONAKION MM PAEDIATRIC to your baby and see a doctor straight away if you notice any of the following serious side effects – your baby may need urgent medical treatment:

Allergic reactions

The signs may include:

- Swelling of your baby's throat, face, lips and mouth. This may make it difficult for them to breathe or swallow.
- Sudden swelling of your baby's hands, feet and ankles.

The following effect may occur at any time during your baby's treatment:

A reaction where the injection was given

Rarely this may be severe. Signs include redness, swelling, pain and it may cause a scar.

If you are concerned about these or any other unexpected effect(s), talk to your doctor. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Not all side-effects reported for KONAKION MM PAEDIATRIC are included in this leaflet. Should your baby's general health worsen while taking KONAKION MM PAEDIATRIC, consult your midwife, doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF KONAKION MM

- KONAKION MM PAEDIATRIC ampoules must be stored at a temperature below 25 °C.
- The ampoules must be stored in their original packaging to protect them from light.
- Keep out of the reach and sight of children.
- Do not use KONAKION MM PAEDIATRIC after the expiry date (EXP) stated on the pack.
- Do not throw away any left-over ampoules. Instead, return them to your pharmacist so that they can be disposed of carefully. Only keep them if your doctor tells you to.

7. PRESENTATION OF KONAKION MM PAEDIATRIC

5 amber glass ampoules each containing 0,2 mℓ solution and 5 dispensers for oral administration.

8. IDENTIFICATION OF KONAKION MM PAEDIATRIC

Ampoules containing a clear to slightly opalescent, greenish yellow solution for oral or parenteral administration.

9. REGISTRATION NUMBER

KONAKION MM PAEDIATRIC 2 mg/ 0,2 ml Ampoules: 29/22/0492

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Pharmaco Distribution (Pty) Ltd.

3 Sandown Valley Crescent,

South Tower, 1st Floor,

Sandton 2196,

South Africa.

11. DATE OF PUBLICATION

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