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Package leaflet: Information for the patient

Pabal[®]

100 micrograms/ml solution for injection Carbetocin

Read all of this leaflet carefully before you are given an injection of Pabal because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, midwife or nurse.
- If you get any side effects, tell your doctor, midwife or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pabal is and what it is used for
2. What you need to know before you are treated with Pabal
3. How Pabal is given to you
4. Possible side effects
5. How Pabal is stored
6. Contents of the pack and other information

1 What Pabal is and what it is used for

Pabal is used to treat women who have just had a baby by caesarean section. In some women, after a caesarean, the womb (uterus) doesn't contract (shrink) quickly enough. This makes it more likely that they'll bleed more than normal. Pabal makes the womb contract and so reduces the risk of bleeding.

The active ingredient in Pabal is carbetocin. It is similar to a substance called oxytocin, which is naturally produced by the body to make the womb contract during childbirth.

2 What you need to know before you are treated with Pabal

Pabal must not be given until after the baby has been delivered.

Before giving Pabal, your doctor needs to know about any medical conditions you may have. You should also tell your doctor about any new symptoms that develop while you are being treated with Pabal.

Pabal must not be used

- if you are allergic to carbetocin or any of the ingredients of Pabal (see Section 6)
- if you have any disease of the liver or kidneys
- if you have pre-eclampsia (high blood pressure in pregnancy) or eclampsia (toxaemia of pregnancy)
- if you have any serious heart disease
- if you have epilepsy
- if you ever have had an allergic reaction to oxytocin (sometimes given as a drip or injection during or after labour)

If any of these apply to you, tell your doctor.

Doctors need to take special care when using Pabal

- if you get migraines
- if you have asthma
- if you have problems with your heart or your circulation (such as high blood pressure)
- if you have any other medical condition

If any of these apply to you, tell your doctor.

Children: Not relevant

Other medicines and Pabal

Tell your doctor if you are taking, or have recently taken, any other medicines - including medicines obtained without a prescription.

Pregnancy and breast-feeding

Pabal must not be used during pregnancy, but may be given after delivery by Caesarean section.

Small amounts of carbetocin have been shown to pass from the nursing mother's blood into the breast milk, but it is assumed to be degraded in the infant's bowels.

3 How Pabal is given to you

Pabal is given as an injection into one of your veins, immediately after your baby has been delivered by caesarean section under an epidural or spinal anaesthetic. The dose is one vial (100 micrograms).

If someone is given too much Pabal

If you are accidentally given too much Pabal, your womb may contract strongly enough to become damaged or to bleed heavily. You may also suffer drowsiness, listlessness and headache, caused by water building up in your body. You will be treated with other medication, and possibly surgery.

4 Possible side effects

Like all medicines, Pabal can have side effects, but not everybody gets them.

The most common side effects may affect at least 10 of every 100 women treated with Pabal. They include:

- nausea
- pain in the stomach
- itching
- flushing (red skin)
- feeling warm
- low blood pressure
- headaches
- shakiness

Other side effects, which may affect between 1 and 10 of every 100 women, include:

- vomiting
- dizziness
- pain in the back or chest
- a metallic taste in the mouth
- anaemia
- breathlessness
- chills

Infrequently some women might experience rapid heartbeat or sweating.

Pabal may cause a build up of water in the body which can lead to drowsiness, listlessness and headache.

Reporting of side effects

If you get any side effects, talk to your doctor, midwife or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme; Website: www.mhra.gov.uk/yellowcard

Ireland: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2.

Tel: +353 1 6764971; Fax: +353 6762517;

Website: www.hpra.ie; E-mail: medsafety@hpra.ie

5 How Pabal is stored

Pabal vials are stored in the outer carton in order to protect from light. Store below 30°C. Do not freeze.

Only clear solutions practically free from particles should be used.

Pabal must not be used after the expiry date printed on the carton and vial.

Pabal should be kept out of sight and reach of children.

6 Contents of the pack and other information

What Pabal contains

The active substance is carbetocin. Each millilitre contains 100 micrograms of carbetocin. The other ingredients are L-methionine, succinic acid, mannitol, sodium hydroxide and water for injections.

What Pabal looks like and contents of the pack

Pabal is clear colourless solution for injection, ready for intravenous injection, supplied in packs of five vials of 1ml.

Pabal should be used only in well equipped specialist obstetrics units.

Marketing Authorisation Holder

UK marketing authorisation holder - PL 03194/0058

Ferring Pharmaceuticals Ltd., Drayton Hall, Church Road, West Draton, UB7 7PS, UK.

Irish product authorisation holder - PA 1009/21/1

Ferring Ireland Ltd., United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24.

Manufacturer

Ferring GmbH, Wittland 11, D-24109 Kiel, Germany.

This medical product is authorised in other Member States of the EEA under the following names: Pabal / DURATOCIN / DURATOBAL

This leaflet was last revised in April 2016.

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