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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 this medicine 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, talk to 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 given Pabal
3. How you are given Pabal
4. Possible side effects
5. How to store Pabal
6. Contents of the pack and other information

1 What Pabal is and what it is used for

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.

Pabal is used to treat women who have just had a baby. In some women, after delivery, 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.

2 What you need to know before you are given Pabal

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

Before giving you 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.

You must not be given Pabal

- if you are pregnant.
- if you are in labour and the baby has not been delivered.
- to induce labour.
- if you are allergic to carbetocin or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to oxytocin (sometimes given as a drip or injection during or after labour).
- if you have any disease of the liver or kidneys.
- if you have any serious heart disease.
- if you have epilepsy.

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

Warnings and precautions

Talk to your doctor, midwife or nurse before you are given Pabal

- if you get migraines.
- if you have asthma.
- if you have pre-eclampsia (high blood pressure in pregnancy) or eclampsia (toxaemia of pregnancy).
- 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, midwife or nurse.

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

Children and adolescents

Not relevant in children below 12 years of age.
The experience with adolescents is limited.

Other medicines and Pabal

Tell your doctor, midwife or nurse if you are taking, have recently taken or might take any other medicines.

Pregnancy and breastfeeding

Do not use Pabal during pregnancy and labour until after the baby has been delivered. 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. Breastfeeding does not need to be restricted after the use of Pabal.

3 How you are given Pabal

Pabal is given as an injection into one of your veins or into one of your muscles, immediately after your baby has been delivered. The dose is one vial (100 micrograms).

If you are given more Pabal than you should have been given

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, this medicine can cause side effects, although not everybody gets them.

When Pabal is given into one of your veins after caesarian section

Very common: may affect more than 1 in 10 people

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

Common: may affect up to 1 in 10 people

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

Not known: frequency cannot be estimated from the available data

- fast heartbeat

Side effects seen with similar products that might be expected with carbetocin:

Slow heartbeat, irregular heartbeat, chest pain, fainting or palpitations which may mean the heart is not beating properly.

Infrequently some women might experience sweating.

When Pabal is given into one of your muscles after vaginal delivery

Uncommon: may affect up to 1 in 100 people

- nausea
- pain in the stomach
- vomiting
- low blood pressure
- anaemia
- headaches
- dizziness
- rapid heartbeat
- pain in the back or chest
- muscle weakness
- chills
- fever
- general pain

Rare: may affect less than 1 in 1,000 people

- flushing (red skin)
- itching
- breathlessness
- shakiness
- difficulty to pass urine

Side effects seen with similar products that might be expected with carbetocin:

Slow heartbeat, irregular heartbeat, chest pain, fainting or palpitations which may mean the heart is not beating properly.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

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

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

5 How to store Pabal

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.

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

The solution should be used immediately after opening of the vial.

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 or intramuscular injection, supplied in packs of five vials of 1 ml.

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

This leaflet was last approved in October 2019.

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