PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PABAL® Carbetocin 100 micrograms per ml solution for injection

Carbetocin

Sugar free

Read all of this leaflet carefully before you are given an injection of PABAL®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist or other healthcare provider.

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. After a single injection it makes the womb contract for several hours following childbirth, without the need for an infusion (drip).

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.

PABAL® will only be administered to you soon after the baby has been delivered.

2. What you need to know before you use PABAL®

PABAL® should not be administered to you:

- **Until after the baby has been delivered.**
- If you are pregnant.
- If you are in labour and the baby has not been delivered.
- To start (induce) labour.
- If you are hypersensitive (allergic) to carbetocin or any of the ingredients of PABAL® (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.

Before giving you PABAL®, your doctor needs to know about any medical conditions you may have (see Warnings and precautions). You should also tell your doctor about any new symptoms that develop while you are being treated with PABAL®.

Warnings and precautions

Tell your doctor or healthcare provider before being given the PABAL® injection if:

- you have pre-eclampsia (high blood pressure in pregnancy) or eclampsia (toxaemia of pregnancy)
- you get migraine
- you have asthma
- you have problems with your heart or your circulation (such as high blood pressure)
- 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

PABAL® is not used in children below 12 years of age.

Other medicines and PABAL®

Always tell your healthcare provider if you are taking any other medicine (This includes all complementary or traditional medicines).

Pregnancy, breastfeeding and fertility

Do not use PABAL® during pregnancy and labour until after the baby has been delivered.

Pregnancy

PABAL® should not be used during pregnancy and labour until after the baby has been delivered.

Breastfeeding

Small amounts of PABAL® 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®.

Driving and using machines

Not relevant.

3. How to use PABAL®

PABAL® will be given to you by your doctor, nurse or midwife 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

Since a healthcare provider will administer PABAL®, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

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 from 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

PABAL® can have side effects.

Not all side effects reported for PABAL® are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while being treated with PABAL®, please consult your healthcare provider for advice.

If any of the following happens, stop using PABAL®, and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to PABAL®. You may need urgent medical attention or hospitalisation.

When PABAL® is given into one of your veins after a caesarean section

Frequent side effects:

- Nausea
- pain in the stomach
- itching

- flushing (red skin)
- feeling warm
- low blood pressure
- headaches
- shakiness
- vomiting
- dizziness
- pain in the back or chest
- a metallic taste in the mouth
- anaemia
- breathlessness
- chills
- general pain.

Less frequent side effects:

- sweating

Frequency not known (cannot be estimated from the available data):

- fast heartbeat
- slow heartbeat
- irregular heartbeat
- chest pain
- fainting
- palpitations which may mean the heart is not beating properly
- allergic reactions (including sudden, severe allergic reaction with breathing difficulty, swelling, light-headedness, fast heartbeat, sweating, low blood pressure and loss of consciousness).

When PABAL® is given into one of your muscles after vaginal delivery

Less frequent side effects:

- anaemia
- headache
- dizziness
- rapid heartbeat
- low blood pressure
- pain in the back or chest
- nausea
- stomach pain
- vomiting
- muscle weakness
- chills
- fever
- general pain
- shakiness
- flushing (red skin)
- difficulty breathing
- itching
- difficulty to pass urine.

Frequency not known (cannot be estimated from the available data):

- slow heartbeat
- irregular heartbeat
- chest pain
- fainting
- palpitations which may mean the heart is not beating properly

- allergic reactions (including sudden, severe allergic reaction with breathing difficulty, swelling, light-headedness, fast heartbeat, sweating, low blood pressure and loss of consciousness).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of PABAL®.

5. How to store PABAL®

- PABAL® vials are stored in the outer carton in order to protect from light.
- Store at or below 30 °C. Do not freeze.
- PABAL® must not be used after the expiry date printed on the carton and vial.
- Do not use PABAL® if you notice visible particulate matter or discoloration of the solution.
- Once the vial has been opened, the product must be used immediately.
- Store all medicines out of reach of children.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PABAL® contains

The active substance is carbetocin.

The other ingredients are L-methionine, succinic acid, mannitol, sodium hydroxide 2M for pH adjustment and water for injection.

What PABAL® looks like and contents of the pack

PABAL® is a clear, colourless solution.

PABAL® is a 1 ml solution containing 100 micrograms carbetocin in colourless, Type I glass vials (2R) with Type I bromobutyl stoppers and an aluminium crimp cap. PABAL® is presented as 5 vials per unit carton.

Holder of Certificate of Registration

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