PATIENT INFORMATION LEAFLET (PIL)

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

CARBETOCIN FERRING 100 micrograms/ml solution for injection
carbetocin

Read all of this leaflet carefully before you are given this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. WHAT CARBETOCIN FERRING IS AND WHAT IT IS USED FOR
The active ingredient in CARBETOCIN FERRING is carbetocin. It is similar to a substance called oxytocin, which is naturally produced by the body to make the womb contract during childbirth.

CARBETOCIN FERRING 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. CARBETOCIN FERRING makes the womb contract and so reduces the risk of bleeding.

2. BEFORE YOU ARE GIVEN CARBETOCIN FERRING
CARBETOCIN FERRING must not be given until after the baby has been delivered.
Before giving you CARBETOCIN FERRING, 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 CARBETOCIN FERRING.

You must not be given CARBETOCIN FERRING
- 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.

Take special care with CARBETOCIN FERRING
- 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.

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

CARBETOCIN FERRING contains sodium as excipient
This medicine contains less than 1 mmol sodium (23 mg) per 100 micrograms/ml, that is to say essentially “sodium-free”.

Taking other medicines
Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
Do not use CARBETOCIN FERRING during pregnancy and labour until after the baby has been delivered.
Small amounts of carbetocin have been shown to pass from the nursings 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 CARBETOCIN FERRING.

Driving and using machines
No studies of the effect on the ability to respond, to drive and to use machines have been conducted. However, carbetocin can have undesirable effects such as dizziness that could impair the ability to drive.

3. HOW YOU ARE GIVEN CARBETOCIN FERRING

CARBETOCIN FERRING 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 ampoule (100 micrograms).

If you are given more CARBETOCIN FERRING than you should have been given
If you are accidentally given too much CARBETOCIN FERRING, 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, CARBETOCIN FERRING can cause side effects, although not everybody gets them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

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
- sweating
- general pain

Uncommon: may affect up to 1 in 100 people
- fast heartbeat

Not known: frequency cannot be estimated from the available data
- hypersensitivity reactions

5. HOW TO STORE CARBETOCIN FERRING

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

Keep the ampoules in the outer carton in order to protect from light.
Store below 30 ºC. Do not freeze.

Do not use CARBETOCIN FERRING after the expiry date which is stated on the carton and ampoule. The expiry date refers to the last day of that month.

The solution should be used immediately after opening the ampoule.

6. FURTHER INFORMATION

What CARBETOCIN FERRING contains:

- The active pharmaceutical ingredient 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 CARBETOCIN FERRING looks like and contents of the pack:
CARBETOCIN FERRING is clear, colourless, sterile solution for injection, ready for intravenous or intramuscular injection, supplied in packs of 10 ampoules of 1 ml.

CARBETOCIN FERRING should be used only in well-equipped specialist obstetrics units.

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IDA Foundation Nigeria.

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