Package leaflet: Information for the patient

Carbetocin 100 micrograms
solution for injection in pre-filled syringe
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 Carbetocin is and what it is used for
2. What you need to know before you are given Carbetocin
3. How you are given Carbetocin
4. Possible side effects
5. How to store Carbetocin
6. Contents of the pack and other information

1. What Carbetocin is and what it is used for
Carbetocin contains the active substance carbetocin. It is similar to a substance called oxytocin, which is naturally produced by the body to make the womb contract during childbirth.

Carbetocin 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 makes the womb contract and so reduces the risk of bleeding.

2. What you need to know before you are given Carbetocin

Carbetocin must not be given until after the baby has been delivered.
Before giving you Carbetocin, 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.

You must not be given Carbetocin:
- 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 Carbetocin.
- 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 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 Carbetocin
Tell your doctor, midwife or nurse if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
Do not use Carbetocin 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 Carbetocin.

Driving and using machines
Not relevant.

Carbetocin contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per mL, i.e. essentially 'sodium-free'.

3. How you are given Carbetocin

Carbetocin is given as injection into one of your veins or into one of your muscles, immediately after your baby has been delivered. The dose is one pre-filled syringe (100 micrograms).

If you are given more Carbetocin than you should have been given
If you are accidentally given too much Carbetocin, 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 Carbetocin 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, slow heartbeat which may lead to cardiac arrest (when the heart stops beating)

Side effects seen with similar products that might be expected with carbetocin:
irregular heartbeat, chest pain, fainting or palpitations which may mean the heart is not beating properly.

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

Infrequently some women might experience sweating.

When Carbetocin 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 the 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.

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

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carbetocin

Keep this medicine out of sight and reach of children.

Carbetocin pre-filled syringes are stored in the outer carton in order to protect from light. Store in a refrigerator (2ºC – 8ºC).

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

6. Contents of the pack and other information

What Carbetocin contains
- The active substance is carbetocin. Each pre-filled syringe contains 1 mL with 100 micrograms of carbetocin.
- The other ingredients are sodium chloride, glacial acetic acid for pH adjustment, water for injections.

What Carbetocin looks like and contents of the pack
Carbetocin is a clear and colourless solution for injection in pre-filled syringe, ready for intravenous or intramuscular injection and it is supplied in packs that contain five pre-filled syringes of 1 mL.

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

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