Package leaflet: Information for the patient

Carbetocin EVER Pharma 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 Carbetocin EVER Pharma is and what it is used for
2. What you need to know before you are given Carbetocin EVER Pharma
3. How you are given Carbetocin EVER Pharma
4. Possible side effects
5. How to store Carbetocin EVER Pharma
6. Contents of the pack and other information

1. What Carbetocin EVER Pharma is and what it is used for

The active ingredient in Carbetocin EVER Pharma 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 EVER Pharma 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 EVER Pharma makes the womb contract and so reduces the risk of bleeding.

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

Carbetocin EVER Pharma must not be given until after the baby has been delivered.

Before giving you Carbetocin EVER Pharma, 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 EVER Pharma.

You must not be given Carbetocin EVER Pharma
- 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 EVER Pharma

- 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 EVER Pharma 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 EVER Pharma
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 EVER Pharma 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.
Breast-feeding does not need to be restricted after the use of Carbetocin EVER Pharma.

Carbetocin EVER Pharma contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 1 ml ampoule/vial, that is to say essentially 'sodium-free'.

3. How you are given Carbetocin EVER Pharma

Carbetocin EVER Pharma 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/vial (100 micrograms).

If you are given more Carbetocin EVER Pharma than you should have been given

If you are accidentally given too much Carbetocin EVER Pharma, 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 EVER Pharma 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)
- allergic reactions (including sudden, severe allergic reaction with breathing difficulty, swelling, light-headedness, fast heartbeat, sweating, low blood pressure and loss of consciousness)

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, light-headedness, fast heartbeat, sweating, low blood pressure and loss of consciousness).

Infrequently some women might experience sweating.

When Carbetocin EVER Pharma 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

Not known: frequency cannot be estimated from the available data
- allergic reactions (including sudden, severe allergic reaction with breathing difficulty, swelling, light-headedness, fast heartbeat, sweating, low blood pressure and loss of consciousness)

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 via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carbetocin EVER Pharma

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, vial and ampoule after EXP. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Store below 30°C.

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

6. Contents of the pack and other information

What Carbetocin EVER Pharma contains
- The active substance is carbetocin. Each millilitre contains 100 micrograms of carbetocin.
- The other ingredients are sodium dihydrogenphosphate dihydrate, sodium acetate trihydrate, mannitol, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment), water for injections

What Carbetocin EVER Pharma looks like and contents of the pack

Carbetocin EVER Pharma is clear colourless solution for injection (injection), ready for intravenous or intramuscular injection, supplied in packs of one or five ampoules or vials of 1 ml.

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

Marketing Authorisation Holder
EVER Valinject GmbH
Oberburgau 3
4866 Unterach am Attersee
Austria

Manufacturer
EVER Pharma Jena GmbH
Brüsseler Str. 18
07747 Jena
Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:

	Name
AT	Carbetocin EVER Pharma 100 Mikrogramm/ml Injektionslösung
BE	Carbetocine EVER Pharma 100 microgram/ml oplossing voor injectie Carbetocine EVER Pharma 100 microgrammes/ml solution injectable Carbetocine EVER Pharma 100 Mikrogramm/ml Injektionslösung
BG	Карбетоцин EVER Pharma 100 µg/ml инжекционен разтвор
CZ	Carbetocin EVER Pharma
DE	Carbetocin EVER Pharma 100 µg/ml Injektionslösung
DK	Carbetocin EVER Pharma
EE	Carbetocin EVER Pharma
ES	Carbetocin EVER Pharma 100 µg/ml solución inyectable EFG
FI	Carbetocin EVER Pharma 100 mikrog/ml injektioneste, liuos
FR	CARBETOCINE EVER PHARMA 100 microgrammes/ml, solution injectable
GR	Carbetocin/EVER Valinject
HR	Karbetocin EVER Pharma 100 mikrograma/ml otopina za injekciju
HU	Carbetocin EVER Pharma 100 mikrogramm/ml oldatos injekció
IE	Carbetocin EVER Pharma 100 micrograms/ml solution for injection
IT	Carbetocina EVER Pharma
LT	Carbetocin EVER Pharma 100 mikrogramų/ml injekcinis tirpalas
LV	Carbetocin EVER Pharma 100 mikrogrami/ml šķīdums injekcijām
NL	Carbetocine EVER Pharma 100 microgram/ml oplossing voor injectie
NO	Carbetocin EVER Pharma
PL	Carbetocin EVER Pharma
PT	Carbetocina EVER Pharma
RO	Carbetocin EVER Pharma 100 microgram̆e/ml soluție injectabilă
SE	Carbetocin EVER Pharma
SI	Karbetocin EVER Pharma 100 µg/ml raztopina za injiciranje
SK	Carbetocin EVER Pharma 100 µg/ml injekčný roztok

This leaflet was last revised in July 2026.