
Carbetocina GP-Pharm 100 mcg

Injectable solution
in pre-filled syringe

**Giving birth with
high safety
does matter**

***Prevention of the
Uterine Atony
after Cesarean section,
is needed to save life.***



GP Pharm

www.gp-pharm.com

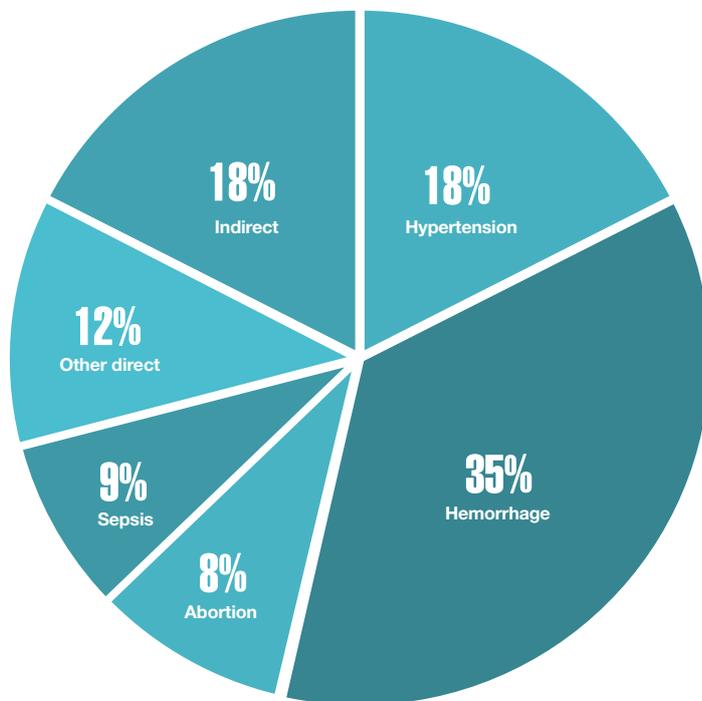


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Uterine atony

The leading cause of maternal mortality is postpartum hemorrhage (PPH).

70% are caused by uterine atony⁽³⁾.



Prevalence and risk

- The risk is much higher in women who have undergone Cesarean section⁽⁴⁾.
- A cesarean section is, in itself, a risk factor independent of PPH⁽⁵⁾.
- In Spain, postpartum hemorrhage causes 23% of all deaths maternal (7.5 cases per 100,000 live births)⁽⁶⁾.

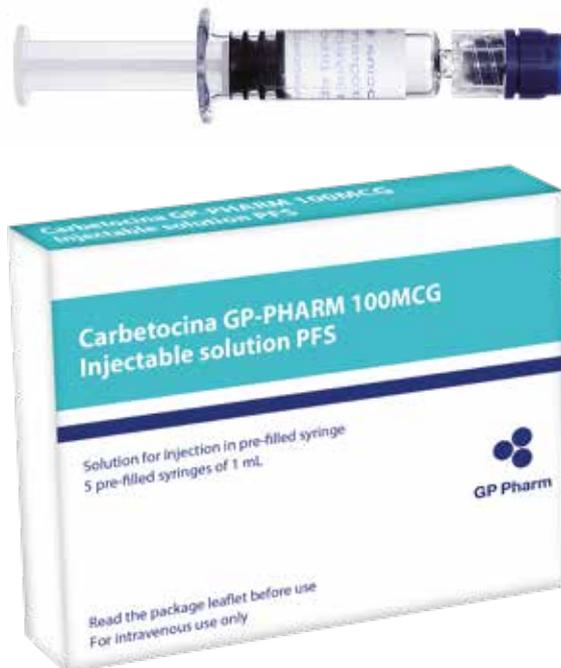
UTEROTONICS AGENTS HISTORICAL EVOLUTION⁽¹⁾

1600	1935	1953	1997	2007
Alkaloids Ergot of rye (Claviceps purpurea)	Ergometrine	Oxytocin	Carbetocin Authorization in UK and Canada.	Carbetocin Carbetocin Authorization in 23 European countries *

(3) Gizzo S, Patrelli TS, Gangi SD, Carrozzini M, et al. Which Uterotonic is better to prevent the postpartum hemorrhage? Latest News in Terms of Clinical Effects, Side Effects, and Contraindications: A Systematic Review. *Reprod Sci* 2013 Jan 7 (Epub ahead of print). (4) Rath Prevention of postpartum haemorrhage with the oxytocin analogue carbetocin. *Eur J Obstet Gynecol Reprod Biol.* 2009 Nov; 147 (1): 15-20. Epub 2009 Jul 17. Review. (5) Higgins L, Mechery J, TomLinson AJ. Does carbetocin for prevention of postpartum haemorrhage at caesarean section provide clinical or nancial bene t compared with oxytocin? *J Obstet Gynaecol.* 2011 Nov; 31 (8): 732-9. (6) Herráiz MA. www.natalben.com/pregnancy-tests-and-ultrasound/prevent-bleeding-postpartum-the-great-unknown. Posted Dec 28 2012.

CARBETOCINA® PROVIDES CLINICAL BENEFITS

- Carbetocina® is a peptide analog (8aa) of oxytocin (9aa).
- Carbetocina® is an oxytocin analog that delays uterine atony after Cesarean section under anesthesia epidural or spinal⁽⁷⁾.
- Carbetocina® can be used in cases of PPH after vaginal delivery⁽⁸⁾.

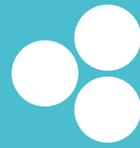


CARBETOCINA® GP-PHARM

- Easy to handle.
- Ready to use.
- For intravenous or intramuscular administration
 - For IV must be administered slowly over 1 minute directly after delivery
- No need of extra manipulation.
- Storage Conditions:
2-8°C (Cold Chain)
25±2°C (for 1 month)
- Shelf life: 36 months.

(7) Carbetocin GP-Pharm. Product data sheet. Revision May 2016.
(8) McDonald S. Management of the third stage of labor. J Midwifery Women's Health. 2007 May-Jun; 52 (3): 254-61. Review.

The period after the birth of the baby and early postpartum are crucial when it comes to prevention, diagnosis and management of postpartum hemorrhage (PPH).



GP Pharm

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(Barcelona) Spain

Data Sheet

Package leaflet: Information for the patient

Carbetocina GP-PHARM 100MCG Injectable solution PFS

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

1. What CARBETOCINA GP-PHARM is and what it is used for

CARBETOCINA GP-PHARM 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.

CARBETOCINA GP-PHARM 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. CARBETOCINA GP-PHARM makes the womb contract and so reduces the risk of bleeding.

2. What you need to know before you are given CARBETOCINA GP-PHARM

CARBETOCINA GP-PHARM must not be given until after the baby has been delivered.

Before giving you CARBETOCINA GP-PHARM, 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 CARBETOCINA GP-PHARM.

You must not be given CARBETOCINA GP-PHARM :

- 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 CARBETOCINA GP-PHARM.

- 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.

CARBETOCINA GP-PHARM 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 CARBETOCINA GP-PHARM

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 CARBETOCINA GP-PHARM 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 CARBETOCINA GP-PHARM.

Driving and using machines

Not relevant.

How you are given CARBETOCINA GP-PHARM

CARBETOCINA GP-PHARM 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 CARBETOCINA GP-PHARM than you should have been given
 - If you are accidentally given too much CARBETOCINA GP-PHARM, 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.
 - Possible side effects

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

When CARBETOCINA GP-PHARM 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 CARBETOCINA GP-PHARM 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.

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 to be completed nationally. By reporting side effects you can help provide more information on the safety of this medicine.

- How to store CARBETOCINA GP-PHARM

Keep this medicine out of sight and reach of children.

CARBETOCINA GP-PHARM pre-filled syringes are stored in the outer carton in order to protect from light. Store in a refrigerator (2°C – 8°C).

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 CARBETOCINA GP-PHARM 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 CARBETOCINA GP-PHARM looks like and contents of the pack

CARBETOCINA GP-PHARM 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. CARBETOCINA GP-PHARM should be used only in well-equipped specialist obstetrics units.

Marketing Authorisation Holder and Manufacturer MPC PHARM.

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This leaflet was last revised in June 2020.

