

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[RH095 trade name] †
Carbetocin

The warnings and instructions in this leaflet are intended for the person taking the medicine.

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 questions about the medicine, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4

What is in this leaflet

1. What [RH095 trade name] is and what it is used for
2. What you need to know before you are given [RH095 trade name]
3. How [RH095 trade name] is given
4. Possible side effects
5. How to store [RH095 trade name]
6. Contents of the pack and other information

1. What [RH095 trade name] is and what it is used for

[RH095 trade name] is used to prevent excessive bleeding after childbirth.

[RH095 trade name] contains the active ingredient carbetocin. It is similar to a substance called oxytocin, which is naturally produced by the body that contracts (shrinks) the womb (uterus) during childbirth.

In some women, the womb doesn't contract quickly enough after giving birth. This makes it more likely that they will bleed more than normal. [RH095 trade name] contracts the womb and so reduces the risk of bleeding.

2. What you need to know before you are given [RH095 trade name]

You will only be given [RH095 trade name] very soon after the birth of your baby.

Before giving you [RH095 trade name] your health care provider needs to know about any medical conditions you may have. You should also tell the health care provider about any new symptoms that develop while you are being treated with [RH095 trade name].

You must not be given [RH095 trade name]

- if you are pregnant
- if you are in labour and the baby has not yet been delivered
- to induce labour
- if you are allergic to carbetocin or any of the other ingredients of the medicine (see section 6)
- if you are allergic to the similar medicine 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 serious heart disease

†Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- if you have epilepsy.

If any of these apply to you, tell your health care provider.

Warnings and precautions

Talk to your health care provider before you are given [RH095 trade name]:

- if you get migraines
- if you have asthma
- if you have pre-eclampsia (high blood pressure during pregnancy) or eclampsia (also called 'toxaemia of pregnancy')
- if you have problems with your heart or circulation (such as high blood pressure)
- if you have any other medical condition
- if you get unwanted effects such as slow heartbeat, irregular heartbeat, chest pain, fainting or palpitations

If any of these apply to you, tell your health care provider.

[RH095 trade name] may cause a build-up of water in your body and in the head, which can lead to drowsiness, listlessness and headache. Tell your health care provider straight away if you start to get these symptoms.

[RH095 trade name] will be used only in obstetric units by skilled and trained health care providers.

[RH095 trade name] contains sodium

This medicine contains less than 1 mmol (23 mg) sodium in each 100-microgram ampoule, that is to say it is essentially "sodium-free".

Other medicines and [RH095 trade name]

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

Pregnancy and breastfeeding

Your health care provider will give you an injection of [RH095 trade name] as soon as your baby has been delivered.

You can breastfeed after treatment with [RH095 trade name]. Small amounts of the active ingredient, carbetocin, may pass into your breast milk but it is likely to be destroyed in your baby's gut.

Driving and using machines

Carbetocin can cause dizziness, which may affect the ability to drive.

3. How [RH095 trade name] is given

[RH095 trade name] is given as an injection into a vein or into a muscle immediately after your baby has been delivered. The medicine will be given to you by a skilled and trained health care provider.

The usual dose of [RH095 trade name] is 1 ampoule (100 micrograms).

Use in children and adolescents

[RH095 trade name] is not recommended for children and adolescents aged under 15 years.

If you are given more [RH095 trade name] than you should have received

If you are accidentally given too much [RH095 trade name], your womb may contract strongly and become damaged, or you may bleed heavily. You may also suffer drowsiness, listlessness, and headache, caused by water building up in your body. If this happens, you will be treated with other medication, and possibly surgery.

4. Possible side effects

Like all medicines, [RH095 trade name] can cause side effects, although not everybody gets them.

If you get any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet.

Very common side effects (may affect more than 1 in 10 people)

- nausea
- pain in the belly
- itching
- flushing (red skin)
- feeling of warm
- low blood pressure
- headache
- tremor (shakiness)

Common side effects (may affect up to 1 in 10 people)

- vomiting
- dizziness
- pain in the back or chest or elsewhere in the body
- metallic taste in the mouth
- anaemia (low levels of red blood cells)
- breathlessness
- chills
- sweating

Uncommon side effects (may affect up to 1 in 100 people)

- fast heartbeat

Side effects with unknown frequency

- hypersensitivity (allergic) reactions

Reporting of side effects

If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. You may also be able to report such side effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [RH095 trade name]

Do not store above 30 °C. Keep ampoules in the outer carton, in order to protect from light. Do not freeze.

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

This medicine must not be used after the expiry date stated on the ampoule after “EXP”. The expiry date refers to the last day of that month.

The solution should be used immediately after opening the ampoule.

6. Contents of the pack and other information

What [RH095 trade name] contains:

- The active 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 [RH095 trade name] looks like and contents of the pack

[RH095 trade name] is a clear, colourless, sterile solution for injection, ready for intravenous or intramuscular injection, supplied in packs of 10 ampules of 1 mL.

Marketing authorization holder

Ferring International Center S.A.
Ch. De la vergognausaz 50
1162 St Prex
Switzerland

For Nigeria:
IDA Foundation Nigeria.

Manufacturer

Steril-Gene Life Sciences Private Ltd.
Steril-Gene, 45, Main Road, Mangalam Village,
Villianur, Puducherry 605110, India

Or

Ferring Pharmaceuticals (China) Co., Ltd.
No 6 HuiLind Lu (Ferring Road), National Health Technology Park,
Zhongshan City, Guangdong Province, People's Republic of China

This leaflet was last revised in November 2022

Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/pqweb/medicines>