Package leaflet: Information for the user

Carboprost Alembic 0.25 mg/ml Solution for injection
carboprost

Read all of this leaflet carefully before you start taking 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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- [Product name] should only be used under the supervision of experienced hospital staff.

What is in this leaflet

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

[Product name] contains the active substance carboprost.
[Product name] belongs to a group of medicines called prostaglandins.

[Product name] is used for:
- to induce abortion.
- treat bleeding that occurs within 24 hours of delivery.

2. What you need to know before you take [Product name]

Do not take [Product name]:
- if you are allergic to carboprost or any of the other ingredients of this medicine (listed in section 6).
- if you have a more serious form of urinary tract infection.
- if you have heart, lung, kidney or liver disease.

Talk to your doctor if you have any of the conditions mentioned above.

Warnings and precautions
Tell your doctor if any of the following apply to you to help him or her decide if [Product name] is suitable for you:

- if you have or have had asthma (breathing difficulties)
- if you have high or low blood pressure
- if you have any cardiovascular disease
- if you have any lung, liver or kidney disease
- if you have visual disturbances or increased pressure in the eye
- if you suffer from anaemia, jaundice, diabetes or epilepsy
- if you have a defect on the uterus (scarring)

If you are not sure if any of the above apply to you, talk to your doctor before receiving [Product name].

Other medicines and [Product name]
Tell your doctor or pharmacist if you are taking, have recently taken or might be taking other medicines.
In particular, tell the doctor if you have taken other medicines that stimulate the contraction of the uterus.

Pregnancy and breastfeeding
[Product name] should not be used during pregnancy or while breastfeeding for purposes other than those mentioned in section 1 above.

[Product name] contains benzyl alcohol (see "[Product name] contains benzyl alcohol and sodium").

Driving and using machines

There have been reports of side effects such as dizziness, vertigo and morbid need for sleep which may impair the ability to drive and use machines. Patients should therefore refrain from driving until they know that [Product name] does not affect their ability to drive and use machines.

[Product name] contains benzyl alcohol and sodium

Benzyl alcohol
[Product name] contains 9.45 mg of benzyl alcohol in 1 ml of solution, which corresponds to 9.45 mg/ml of benzyl alcohol.

Benzyl alcohol can cause allergic reactions.

Large amounts of benzyl alcohol can be stored in the body and cause side effects such as an increased amount of acid in the blood (metabolic acidosis). Your doctor will take this into account, especially if you have impaired liver or kidney function or if you are pregnant or breast-feeding.

Sodium
This medicinal product contains less than 1 mmol (23 mg) of sodium per ampoule, i.e. is almost "sodium-free".

3. How to take [Product name]

To induce abortion:
The doctor or nurse will inject the recommended dose into a muscle. The dosage will be repeated every 2-3 hours. In case of unsatisfactory contraction of the uterus, the doctor will adjust the dose and/or how often you receive the injections.

To treat bleeding:
The doctor or nurse will inject the recommended dose into a muscle. One dose is usually enough.

If you have any further questions about this medicine, ask your doctor or nurse.

If you have received overdose of [Product name]
As this medicine is given by a doctor or nurse, you are unlikely to get it overdosed.

The staff will make sure that this medicine is used in the right way and at the right time. If in doubt, ask your doctor or healthcare professional. Only the doctor can change the dose.

4. Possible Side Effects

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

The side effects of [Product name] are temporary and usually disappear after stopping the treatment. The following side effects may occur with this injection:

Very common (may affect more than 1 in 10 people):
- vomiting, diarrhoea
- nausea
- 38°C fever or higher

Common (may affect up to 1 in 10 people):
- headache
- redness, hot flushes, chills
- cough
- bleeding from the abdomen, the placenta or amniotic membranes do not loosen, inflammation and pain in the endometrium due to infection (endometritis)

Uncommon (may affect up to 1 in 100 people):
- septic shock (blood poisoning), urinary tract infection
- sleep disorder, morbid need for sleep (somnolence), abnormal mental fatigue (lethargy)
- dizziness
- muscle movements that affect posture of the body and head
- general muscle pain, numbness, tingling
- neck restraint
- altered taste

- abnormally large sweating
- chest discomfort, asthma and general discomfort of not being able to breathe, labored breathing, shortness of breath, wheezing, hiccups
- pain in the upper part of the abdomen, back pain, pelvic pain
- breast tenderness
- blurred vision, eye pain.
- dry mouth
- feeling dizzy (vertigo)
- tinnitus
- fast heartbeats
- increased blood pressure, drop in blood pressure
- vomiting blood
- uterine rupture, tearing of the cervix
- pain at the injection site

Not known: frequency cannot be estimated from the available data:
- severe hypersensitivity reactions (such as sudden wheezing, difficulty breathing, swollen eyelids, face or lips, rash or itching (especially if it itches all over the body, swollen tissues)
- toxic goiter
- worry, nervousness.
- fainting (due to drop in blood pressure)
- palpitations
- spasm in the muscles of the trachea, edema in the pharynx, feeling of suffocation, nosebleed, dry throat, infection in the upper respiratory tract
- retching
- rash
- muscle spasm, eyelid spasm
- irregular or heavy periods
- chest pain, weakness, thirst

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product name]

[Product name] is stored by healthcare professionals in the hospital or clinic. The storage instructions are as follows; in case you need to know them:

- Keep this medicine out of the sight and reach of children.
- Store and transport refrigerated at 2 – 8°C.
- Do not use this medicine after the expiry date stated on the bottle after EXP/Exp.dat. The expiration date is the last day of the specified 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.

6. Contents of the pack and other information

What [Product name] contains
- The active substance is carboprost trometamol. 1 ml contains 0.25 mg carboprost.
- Other ingredients are: sodium chloride, benzyl alcohol, trometamol, sodium hydroxide/hydrochloric acid (for pH adjustment), water for injection (see section 2 "[Product name] contains benzyl alcohol and sodium").

What [Product name] looks like and contents of the pack
[Product name] solution for injection is a clear, colorless solution, free of visible particulate matter.
[Product name] is available in vials with 1 ml of solution for injection. One pack contains 1 vial.

Marketing Authorisation Holder and Manufacturer:
[To be completed nationally]

This leaflet was last revised in 15 July 2025.