CARBOPROST-REACH

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using CARBOPROST-REACH?

CARBOPROST-REACH contains the active ingredient carboprost trometamol. CARBOPROST-REACH is used to stop excessive bleeding in women who have just given birth, when bleeding is due to the womb failing to return to its normal size.

For more information, see Section 1. Why am I using CARBOPROST-REACH? in the full CMI.

2. What should I know before I use CARBOPROST-REACH?

Do not use if you have ever had an allergic reaction to CARBOPROST-REACH or any of the ingredients listed at the end of the CMI

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use CARBOPROST-REACH? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CARBOPROST-REACH and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. What should I know while using CARBOPROST-REACH?

Things you should do	Remind any doctor, dentist or pharmacist you visit that you have been given CARBOPROST-REACH.
Driving or using machines	Do not drive, use any tools or operate machinery soon after receiving CARBOPROST-REACH as it may affect your ability to do so safely. CARBOPROST-REACH may make you lose consciousness, feel dizzy or drowsy.

For more information, see Section 5. What should I know while using CARBOPROST-REACH? in the full CMI.

5. Are there any side effects?

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

CARBOPROST-REACH

Active ingredient(s): carboprost trometamol

Consumer Medicine Information (CMI)

This leaflet provides important information about using CARBOPROST-REACH. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using CARBOPROST-REACH.

Where to find information in this leaflet:

- 1. Why am I using CARBOPROST-REACH?
- 2. What should I know before I use CARBOPROST-REACH?
- 3. What if I am taking other medicines?
- 4. How do I use CARBOPROST-REACH?
- 5. What should I know while using CARBOPROST-REACH?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using CARBOPROST-REACH?

CARBOPROST-REACH contains the active ingredient carboprost (as trometamol). CARBOPROST-REACH

belongs to a group of medicines called prostaglandins. Prostaglandins are hormone-like substances produced naturally in your body. They act to increase the contractions of your womb and helps control bleeding after you have given birth to your baby.

CARBOPROST-REACH is used to stop excessive bleeding in women who have just given birth, when bleeding is due to the womb failing to return to its normal size.

2. What should I know before I use CARBOPROST-REACH?

Warnings

Do not use CARBOPROST-REACH if:

- you are allergic to carboprost (as trometamol), or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions such as
 - an infection of your womb, ovaries or fallopian tubes (this may be causing pain in your pelvis or vaginal discharge)
 - any problems with your heart, lung, kidney or liver
- are currently taking other similar medicines to help control your contractions and bleeding.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not have this medicine if you are pregnant.

CARBOPROST-REACH contains an ingredient called benzyl alcohol (see list of ingredients at the end of this leaflet), that can cross the placenta. Benzyl alcohol has been associated with serious side effects which can be fatal in children, especially premature and low weight infants. CARBOPROST-REACH should only be given shortly after you have delivered your baby and not while you are still pregnant as it could put the embryo or foetus at risk.

Tell your doctor, nurse or other healthcare provider if you intend to breastfeed your baby.

It is not known if CARBOPROST-REACH is excreted in human breast milk.

You must wait for at least 6 hours after receiving your last dose of CARBOPROST-REACH before breastfeeding your baby.

Do not give this medicine to children.

Tell your doctor, nurse or other healthcare provider if you have or have had any of the following medical conditions:

- lung disease, including asthma
- high or low blood pressure (including high blood pressure in pregnancy)
- heart disease or anaemia (low blood count)
- kidney or liver disease (including jaundice)
- glaucoma (raised pressure in your eyes)
- diabetes or epilepsy
- a caesarean section or any other operation on your womb.

If you have not told your doctor, nurse or other healthcare provider about any of the above, tell him/her before you are given CARBOPROST-REACH.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If you are not sure whether you should be using this medicine, talk to your doctor, nurse or other healthcare provider.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and CARBOPROST-REACH may interfere with each other. These include:

 treatments that strengthen contraction of the womb, including oxytocin and ergometrine.

These medicines may be affected by CARBOPROST-REACH or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CARBOPROST-REACH.

4. How do I use CARBOPROST-REACH?

CARBOPROST-REACH should be used by medically trained staff in hospitals and clinics with specialised obstetric units where 24 hour medical care is available.

How much is given

The dose of CARBOPROST-REACH will be determined by your doctor for your individual requirements.

The first dose is usually 1 mL of solution (250 μg of carboprost). Your doctor may give you more doses of 1 mL if you need them.

You should not have doses more often than once every 15 minutes. Usually you would have them less often, about once in one and-a-half hours.

You should not be given more than 8 doses (2 mg of carboprost) altogether.

How it is given

CARBOPROST-REACH is given by injection deep into a muscle. It must never be given by injection into a vein.

When it is given

Your doctor will determine you long you should be treated. Your doctor will make sure that this medicine is used in the right way and at the right time.

If you are given too much (overdose)

Your doctor has information on how to recognise and treat an overdose.

If you are given too much CARBOPROST-REACH and you are nauseous, vomiting or experience very bad diarrhoea, your doctor may delay the next injection of CARBOPROST-REACH or may not give you any more doses.

If you think you have been given too much CARBOPROST-REACH, talk to your doctor, nurse or other healthcare provider immediately.

If you continue to bleed heavily after being given CARBOPROST-REACH, you may be given other medicines to help control the bleeding. Your doctor, nurse or other healthcare provider will be watching you closely to help them decide whether CARBOPROST-REACH is working for you.

5. What should I know while using CARBOPROST-REACH?

Things you should do

Tell your doctor, nurse or other healthcare provider if you intend to breastfeed your baby.

- It is not known if CARBOPROST-REACH is excreted in human breast milk.
- You should wait for at least 6 hours after receiving your last dose of CARBOPROST-REACH before breastfeeding your baby.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how CARBOPROST-REACH affects you.

Do not drive, use any tools or operate machinery soon after receiving CARBOPROST-REACH as it may affect your ability to do so safely. CARBOPROST-REACH may make you lose consciousness, feel dizzy or drowsy.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Tell your doctor, nurse or other healthcare provider if you notice any of the following and they worry you:

- nausea, vomiting or retching
- dizziness, unsteadiness when walking or spinning sensation
- ringing in the ears
- blurred vision or eye pain
- · abnormal taste
- excessive thirst

- · dry throat or dry mouth
- hiccups
- coughing
- nose bleeds
- flushing
- hot flushes
- tingling or pins and needles in the hands or feet,
 sudden numbness or weakness in the legs or arms
- cramps or muscle spasms
- tenderness of the breasts
- general muscle pain
- stomach or abdominal pain
- back pain, pelvic pain
- feeling of tiredness or lack of energy
- pain or burning during urination
- infection affecting the nose sinuses and throat
- irregular sleep patterns or general feeling of sleepiness or drowsiness
- anxiety
- nervousness
- local reaction around the injection site such as redness, itchiness, tenderness, pain or discomfort, warmth, burning, stinging or swelling.

Tell your doctor, nurse or other healthcare provider immediately if you get any of the following side effects:

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body
- coughing or vomiting up blood, difficulty breathing as a result of fluid retention in the lungs
- chest pain or discomfort
- breathing difficulties such as rapid breathing or wheezing
- high blood pressure
- abdominal pain, vaginal bleeding, rapid pulse rate, chest pains as a result of tearing, wound or cut in the muscles of the womb
- high fever, chills or shivering, headache, rapid heart rate, confusion, rapid breathing as a result of septic shock
- continued heavy bleeding after your child has been delivered as a result of retained placenta or membranes
- temporary loss of consciousness caused by a fall in blood pressure
- swelling of the throat, choking sensation
- · muscle contractions affecting your posture and

- positioning of the head
- uncontrolled abnormal contraction or twitch of the eyelid
- abnormal physical weakness
- diarrhoea, weight loss, rapid heart rate, excessive or increased levels of sweating or perspiration and very high body temperature from a rare but severe form of hyperthyroidism.

These are very serious side effects. You may need urgent medical attention.

Other side effects not listed above may occur in some patients. Tell your doctor, nurse or other healthcare provider if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You or your child may not experience any of them.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What CARBOPROST-REACH contains

Active ingredient	Carboprost trometanol
(main ingredient)	
Other ingredients	sodium chloride
(inactive ingredients)	benzyl alcohol
	trometamol
	hydrochloric acid
	sodium hydroxide
	Water for Injections.

Do not take this medicine if you are allergic to any of these ingredients.

What CARBOPROST-REACH looks like

CARBOPROST-REACH is a clear, colourless solution available in glass ampoules containing 1mL of solution.

CARBOPROST-REACH is supplied in a pack of 10 (AUST R 394092).

Who distributes CARBOPROST-REACH

Reach Pharmaceuticals Ground Floor, Corporate One, 84 Hotham Street, Preston VIC 3072

This leaflet was prepared in June 2023.