

PROSTIN 15M®

Carboprost tromethamine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Prostin 15M.

It does not contain all the available information.

It does not take the place of talking to your doctor, nurse or other healthcare provider.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Prostin 15M against the benefits they expect it will have.

If you have any concerns about taking this medicine, ask your doctor, or nurse.

Keep this leaflet with the medicine.

You may need to read it again.

What Prostin 15M is used for

How it works

Prostin 15M 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.

Prostin 15M 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.

Your doctor may have prescribed it for another reason.

Ask your doctor, nurse or other healthcare provider if you have any questions about why this medicine has been prescribed for you.

Prostin 15M should not be used in children.

This medicine is not addictive.

Do not drive, use any tools or operate machinery soon after receiving Prostin 15M as it may affect your ability to do so safely. Prostin 15 may make you lose consciousness, feel dizzy or drowsy.

Prostin 15M is available only with a doctor's prescription. It should only be used by medically trained staff in hospitals and clinics with specialised obstetric units where 24 hour medical care is available.

Never administer this medicine yourself.

Before you are given Prostin 15M

When you must not be given Prostin 15M

Do not have Prostin 15M if you have an allergy to

- the active ingredient, carboprost tromethamine, or any of the ingredients listed at the end of this leaflet, in particular benzyl alcohol, which can cause problems in some people.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not have Prostin 15M if you:

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

Do not have this medicine if you are pregnant.

Prostin 15M contains an ingredient called benzyl alcohol (see list of ingredients at the end of this leaflet), that can cross the placenta.

Prostin 15M 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 Prostin 15M is excreted in human breast milk.

You must wait for at least 6 hours after receiving your last dose of Prostin 15M before breastfeeding your baby.

Do not give this medicine to children.

Benzyl alcohol has been associated with serious side effects which can be fatal in children, especially premature and low weight infants.

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.

Before you are given it

Tell your doctor, nurse or other healthcare provider if you have allergies to any other medicines, foods, preservatives or dyes.

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 Prostin 15M.

Taking other medicines

Tell your doctor, nurse or other healthcare provider if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Prostin 15M may interfere with each other. These include:

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

These medicines may be affected by Prostin 15M or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor, nurse or other healthcare provider will have more information on medicines to avoid while taking this medicine.

How Prostin 15M should be given

Prostin 15M 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 Prostin 15M 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

Prostin 15M 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 how 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 Prostin 15M and you are nauseous, vomiting or experience very bad diarrhoea, your doctor may delay the next injection of Prostin 15M or may not give you any more doses.

If you think you have been given too much Prostin 15M, talk to your doctor, nurse or other healthcare provider immediately.

If you continue to bleed heavily after being given Prostin 15M, 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 Prostin 15M is working for you.

While you are having Prostin 15M

Things you must do

Talk to your doctor, nurse or other healthcare provider before you are given Prostin 15M if you currently have, or have had in the past any of the following:

- lung disease, including asthma. It is possible that this medicine may lower the oxygen levels in your blood. If you have previously suffered from conditions affecting your heart and lungs your doctor will monitor you and may give you additional oxygen as necessary.
- high or low blood pressure (including high blood pressure in pregnancy)
- heart disease. In very rare cases heart and circulation failure have been reported following the use of prostaglandins (the active ingredient of this medicine).
- 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.

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

It is not known if Prostin 15M is excreted in human breast milk.

You should wait for at least 6 hours after receiving your last dose of Prostin 15M before breastfeeding your baby.

Things to be careful of

You must never be given Prostin 15M while you are still pregnant. You should only be given Prostin 15M after you have delivered your baby.

Do not drive, use any tools or operate machinery soon after receiving Prostin 15M as it may affect your ability to do so safely. Prostin 15 may make you lose consciousness, feel dizzy or drowsy.

Side effects

Tell your doctor, nurse or other healthcare provider as soon as possible if you do not feel well while you are being given Prostin 15M.

All medicines can have unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Medicines can affect people in different ways.

Ask your doctor, nurse or other healthcare provider to answer any questions you may have.

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.

Storing Prostin 15M

Storage

Prostin 15M should be stored in a refrigerator at 2- 8°C at the hospital where you will be treated.

Product description

What it looks like

Prostin 15M is a clear, colourless solution available in glass ampoules containing 1mL of solution.

Prostin 15M is supplied in a pack if 1 ampoule.

Ingredients

Active ingredient:

- carboprost tromethamine.

Other ingredients:

- sodium chloride
- benzyl alcohol
- trometamol
- hydrochloric acid
- sodium hydroxide
- Water for Injections.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Prostin 15M is supplied by:

Pfizer New Zealand Ltd
P O Box 3998
Auckland
New Zealand

Toll Free Number: 0800 736 363.

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