

Duratocin® Injection

Carbetocin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Duratocin.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you having Duratocin against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What Duratocin is used for

Duratocin contains carbetocin, a substance which is an oxytocic agent and causes the womb (uterus) to contract.

Duratocin is used to minimise postdelivery bleeding in women who have delivered their baby vaginally or by caesarean section.

How it works

In some women, following delivery, the womb fails to contract quickly enough which increases the risk of bleeding. Drugs that act directly on the womb to make it contract are used to minimise post-delivery bleeding and are sometimes called oxytocic agents because they act in a similar manner to oxytocin.

Ask your doctor if you have any questions about this medicine.

Your doctor may have prescribed it for another reason.

Duratocin is available only with a doctor's prescription. It is not addictive.

Before you are given Duratocin

When you must not be given it

Duratocin must not be given if you have an allergy to:

- carbetocin, the active ingredient, or to any of the ingredients listed at the end of this leaflet
- any medicines containing oxytocin.

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.

You must not be given Duratocin during pregnancy or any time before delivery of the baby.

Duratocin should only be given after delivery of your baby.

You must not be given Duratocin if you are suffering from serious heart disease.

Duratocin should not be given to children. Safety and effectiveness in children have not been established.

Duratocin must not be given after the expiry date printed on the vials and outer packaging.

Duratocin must not be given if packaging is torn or shows signs of tampering.

If you not sure whether you should be given Duratocin, talk to your doctor.

Before you are given it

Tell your doctor if you have high blood pressure or any heart problems.

Your doctor may want to take extra precautions.

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

Tell your doctor if you have or have had any of the following medical conditions:

- severe heart disease
- high blood pressure
- liver or kidney problems
- problems with blood clotting
- disease of a gland
- gestational diabetes (diabetes that starts during pregnancy)
- epilepsy
- migraine
- asthma.

If you have not told your doctor about any of the above, tell him/ her before you have Duratocin.

Taking other medicines

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

How Duratocin is given

Duratocin is a medicine that is used only in hospital and should only be administered by qualified staff.

Duratocin will be given to you by injection, either into one of your veins or muscles, immediately after the delivery of your baby.

How much you will be given

Duratocin will be given as a single dose of 100 micrograms (1 mL) either injected into one of your muscles or into a vein by injection, slowly over one minute.

Side effects

Tell your doctor or nurse immediately if you do not feel well after you have been given Duratocin.

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

- nausea (feeling sick) or vomiting
- stomach pain
- itching
- flushing or feeling of warmth
- feeling light headed, dizzy or faint (low blood pressure)
- headache
- tremor.

These are the more common side effects of Duratocin. Mostly these are mild and short-lived.

Tell your doctor or nurse immediately if you notice any of the following:

- back pain
- dizziness
- metallic taste
- signs of anaemia, such as tiredness, being short of breath and looking pale
- sweating
- chills
- nervousness, feeling anxious.

All of these side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice the following:

- chest pain
- fast or abnormal heart beat
- shortness of breath
- swelling of the face, lips, tongue or other parts of the body
- cold clammy skin.
- fainting or palpitations

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients.

Tell your doctor or nurse if you notice anything that is making you feel unwell.

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

You may not experience any of them.

Ask your doctor to answer any questions you may have.

After using Duratocin

Storage

Duratocin is usually stored in the doctor's surgery or clinic, or at the pharmacy.

However, if you need to store Duratocin:

Keep it where children cannot reach it.

Keep Duratocin in the original container until it is time for it to be given.

Keep vial in a place where the temperature stays below 30°C.

If you take your medicine out of the original container, it will not keep well.

Product description

What it looks like

Duratocin is a clear colourless solution in a 1 mL clear glass vial.

Ingredients

Duratocin contains 100 micrograms of carbetocin as the active ingredient.

It also contains:

- methionine
- succinic acid
- mannitol
- sodium hydroxide
- water for injections.

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

Sponsor

Duratocin is supplied in Australia by:

Ferring Pharmaceuticals Pty Ltd
Suite 2, Level 1, Building 1
20 Bridge Street

Pymble NSW 2073

Australia

Australian Registration Number:

AUST R 233671 - Duratocin carbetocin 100
microgram/1 mL injection vial

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