DURATOCIN®

Consumer Medicine Information (CMI) summary

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

1. Why am I being given DURATOCIN?

DURATOCIN contains the active ingredient carbetocin. DURATOCIN is used after birth to minimise the risk of bleeding in women who have delivered their baby vaginally or by caesarean section.

For more information, see Section 1. Why am I being given DURATOCIN? in the full CMI.

2. What should I know before I am given DURATOCIN?

Do not use if you have ever had an allergic reaction to carbetocin, oxytocin 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 breastfeeding.

For more information, see Section 2. What should I know before I am given DURATOCIN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DURATOCIN 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. How will I be given DURATOCIN?

- DURATOCIN is a medicine that is used only in hospital and will be given to you by a healthcare professional.
- A single dose of 100 micrograms (1 mL) will either be injected into one of your muscles, or injected slowly over one minute into a vein.

More instructions can be found in Section 4. How will I be given DURATOCIN? in the full CMI.

5. What should I know while using DURATOCIN?

Looking after your medicine	• DURATOCIN is usually stored at the hospital or at the pharmacy. Keep DURATOCIN in the original container until it is time for it to be given, in a place where the temperature stays below 30°C.

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

6. Are there any side effects?

Some common side effects of DURATOCIN are nausea (feeling sick) or vomiting, stomach pain, itching, flushing or feeling of warmth, feeling light headed, dizzy or faint (low blood pressure), headache, and tremor (shaking).

Serious side effects include hypersensitivity and severe allergic reactions, fast or abnormal heart beat, chest pain, cold clammy skin, and fainting or palpitations.

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.

DURATOCIN®

Active ingredient: *carbetocin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DURATOCIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given DURATOCIN.**

Where to find information in this leaflet:

1. Why am I am I being given DURATOCIN?
2. What should I know before I am given DURATOCIN?
3. What if I am taking other medicines?
4. How will I be given DURATOCIN?
5. What should I know while using DURATOCIN?
6. Are there any side effects?
7. Product details

1. Why am I being given DURATOCIN?

DURATOCIN contains the active ingredient carbetocin. Carbetocin is a medicine that causes the womb (uterus) to contract. Such medicines are sometimes called oxytocic agents because they act in a similar manner to oxytocin.

In some women, following delivery, the womb fails to contract quickly enough which increases the risk of bleeding.

DURATOCIN is used after birth to minimise the risk of bleeding in women who have delivered their baby vaginally or by caesarean section.

2. What should I know before I am given DURATOCIN?

Warnings

DURATOCIN must not be given to you if you:

- are allergic to carbetocin, or any of the ingredients listed at the end of this leaflet.
  Always check the ingredients to make sure you can use this medicine.
- are allergic to any medicine containing oxytocin.
- have disorders of the heart and blood vessels.

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

DURATOCIN must only be given after delivery of your baby.

DURATOCIN should not be given to children.

Check with your doctor if you have any other medical conditions such as:

- severe heart disease
- high blood pressure (including eclampsia and pre-eclampsia)
- abnormalities of the placenta
- liver or kidney problems
- problems with blood clotting
- disease of a gland (endocrine disorders)
- gestational diabetes (diabetes that starts during pregnancy)
- migraine
- epilepsy
- asthma.

Tell your doctor if you have previously given birth four or more times.

DURATOCIN is not recommended for use in elderly patients.

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

Breastfeeding

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

3. What if I am taking other medicines?

Tell your doctor, pharmacist or midwife 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.

4. How will I be given DURATOCIN?

DURATOCIN is a medicine that is used only in hospital and will be given to you by a healthcare professional.

How much you will be given

- A single dose of 100 micrograms (1 mL) will either be injected into one of your muscles, or injected slowly over one minute into a vein.

When you will be given DURATOCIN

- DURATOCIN will be given to you immediately after the delivery of your baby.

5. What should I know while using DURATOCIN?

Looking after your medicine

DURATOCIN is usually stored at the hospital or at the pharmacy.

Keep DURATOCIN in the original container until it is time for it to be given, in a place where the temperature stays below 30°C.

Getting rid of any unwanted medicine

Any medicine that it is unused or out of date will be safely disposed of by the hospital.

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 or midwife immediately if you notice any of the following:

- nausea (feeling sick) or vomiting
- stomach pain
- itching
- flushing or feeling of warmth
- feeling light headed, dizzy or faint (low blood pressure)
- headache
- tremor (shaking)
- back pain
- dizziness
- metallic taste
- signs of anaemia, such as tiredness, being short of breath and looking pale
- sweating
- chills
- nervousness, feeling anxious.

Some side effects can be serious, for example:

- hypersensitivity reaction and severe allergic reaction (anaphylactic reaction), which can include: rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- fast, slow or abnormal heart beat
- chest pain
- cold clammy skin
- fainting or palpitations.

These are very serious side effects, which can be life-threatening. They need urgent medical attention.

Tell your doctor, pharmacist or midwife 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 DURATOCIN contains

Active ingredient (main ingredient)	carbetocin
Other ingredients (inactive ingredients)	mannitol succinic acid methionine sodium hydroxide water for injections

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

What DURATOCIN looks like

DURATOCIN is a clear colourless solution for injection in a 1 mL clear glass vial with a rubber stopper and aluminium cap, with a tear-off over cap.

Each 1 mL vial contains carbetocin 100 micrograms.

It is supplied in packs of 5 vials (AUST R 233671).

Who distributes DURATOCIN

DURATOCIN is distributed in Australia by:

Ferring Pharmaceuticals Pty Ltd
Suite 2, Level 1, Building 1
20 Bridge Street
Pymble NSW 2073

DURATOCIN® is a registered trademark of Ferring B.V.

This leaflet was prepared in December 2022.

DOCS#11524-v10