

MARCAIN/MARCAIN with ADRENALINE injection

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.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using MARCAIN?

MARCAIN contains the active ingredient bupivacaine hydrochloride with or without adrenaline (epinephrine). Marcain is used to prevent or relieve pain, but it will not put you to sleep.

For more information, see Section [1. Why am I using MARCAIN?](#) in the full CMI.

2. What should I know before I use MARCAIN?

Do not use if you have ever had an allergic reaction to bupivacaine hydrochloride, adrenaline (epinephrine) 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 are breastfeeding.

For more information, see Section [2. What should I know before I use MARCAIN?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MARCAIN 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 MARCAIN is given?

- MARCAIN will be injected by your doctor into the skin, near a single nerve, or into an area which contains a large number of nerves.
- The dosage you will be given will depend on your body size, age and the type of pain relief required.

More instructions can be found in Section [4. How MARCAIN is given?](#) in the full CMI.

5. What should I know while receiving MARCAIN?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are receiving MARCAIN.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery after you have been given MARCAIN. You may be drowsy and your reflexes may be slow.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol while you are being given MARCAIN. If you drink alcohol while you are being given MARCAIN your blood pressure may drop, making you feel dizzy and faint.
Looking after your medicine	<ul style="list-style-type: none">• MARCAIN will be stored by your doctor or pharmacist under the recommended conditions.• MARCAIN in glass vials should be kept in a cool dry place where the temperature stays below 25°C.• MARCAIN in plastic bags or ampoules should be kept in a cool dry place where the temperature stays below 30 °C.

For more information, see Section [5. What should I know while receiving MARCAIN?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given MARCAIN.

Some of the mild side effects of MARCAIN include nervousness, dizziness, blurred vision, a tingling feeling ("pins and needles"), ringing in the ears, numbness, feeling strange (disoriented), nausea (feeling sick) and vomiting.

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.

MARCAIN/MARCAIN with ADRENALINE injection

Active ingredients: *bupivacaine hydrochloride/bupivacaine hydrochloride with adrenaline (epinephrine)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MARCAIN injection.

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 MARCAIN.

Where to find information in this leaflet:

- [1. Why am I using MARCAIN?](#)
- [2. What should I know before I am given MARCAIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How MARCAIN is given?](#)
- [5. What should I know while receiving MARCAIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using MARCAIN?

MARCAIN injection contains the active ingredient bupivacaine hydrochloride with or without adrenaline (epinephrine). Bupivacaine hydrochloride belongs to a group of medicines called local anesthetics.

This medicine is used to prevent or relieve pain, but it will not put you to sleep. MARCAIN is also used after surgery to relieve pain. It can also be used to make childbirth less painful.

When injected, it makes the nerves nearby unable to pass messages to the brain and will therefore prevent or relieve pain.

Depending on the amount used, MARCAIN will either totally stop pain or will cause a partial loss of feeling.

MARCAIN is sometimes combined with adrenaline (epinephrine) to make it last longer. Adrenaline makes the blood vessels at the site of injection narrower, which keeps the MARCAIN where it is needed for a longer time.

Follow all directions given to you by your doctor carefully.

Your doctor will have explained why you are being treated with MARCAIN and told you what dose you will be given.

Ask your doctor if you have any questions about why this medicine has been given to you.

Your doctor may have decided to give this medicine to you for another purpose.

MARCAIN is not addictive.

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

Warnings

You must not be given MARCAIN if:

- you are allergic to bupivacaine hydrochloride, adrenaline (epinephrine) or any of the ingredients listed at the end of this leaflet.
- you are allergic to other local anaesthetics e.g. lignocaine
- you are pregnant or breastfeeding.

We do not know if it is safe for you to be given it while you are pregnant. It may affect your baby if you take it early in pregnancy or in the last weeks before your baby is due. However, it can be used during childbirth.

Your baby can take in very small amounts of MARCAIN from breast milk if you are breastfeeding, but it is unlikely that the amount available to the baby will do any harm.

- the expiry date printed on the pack has passed.
- the solution is not clear, or the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions:
 - problems with your blood pressure or circulation
 - blood poisoning
 - problems with the clotting of your blood
 - acidosis, or too much acid in the blood.
 - epilepsy
 - nerve problems
 - heart, liver or kidney problems
 - disease of the brain or spine
 - thyrotoxicosis
 - diabetes
 - muscle disease or weakness (e.g. myasthenia gravis).

It may not be safe for you to be given MARCAIN if you have any of these conditions.

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.

We do not know if it is safe for you to be given it while you are pregnant. It may affect your baby if you take it early in pregnancy or in the last weeks before your baby is due. However, it can be used during childbirth.

Your baby can take in very small amounts of MARCAIN from breast milk if you are breastfeeding, but it is unlikely that the amount available to the baby will do any harm.

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 MARCAIN may interfere with each other. These include:

- medicines that control your heart beat
- medicines used to thin the blood, including aspirin
- low molecular weight heparin or other medicines used to prevent blood clots
- medicines for depression
- medicines that you buy at the chemist, supermarket or health food shop.

Your doctor or pharmacist can tell you what to do if you are taking any of these 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 MARCAIN.

4. How MARCAIN is given?

How much is given

The dosage will depend on your body size, age and the type of pain relief required.

Your doctor will have had a lot of experience injecting MARCAIN or other local anaesthetics and will choose the best dose for you.

How MARCAIN is administered

MARCAIN will be injected by your doctor into the skin, near a single nerve, or into an area which contains a large number of nerves.

This will result in an area of numbness at the site of injection, near the site of injection or in an area that may seem unrelated to the site of injection e.g. an epidural injection (an injection into the epidural space between vertebrae around the spinal cord in the lower back resulting in a feeling of numbness in the lower body. A thin tube will be inserted so a continuous dose can be given over a period of time).

MARCAIN should not be injected directly into the blood.

If you are given too much MARCAIN

The doctor giving you MARCAIN will be experienced in the use of local anaesthetics, so it is unlikely that you will be given an overdose.

However, if you are particularly sensitive to MARCAIN, or the dose is accidentally injected directly into your blood, you may develop problems for a short time with your sight or hearing. You may get a numb feeling in or around the mouth, feel dizzy or stiff, or have twitchy muscles.

Whenever you are given MARCAIN, equipment will be available to revive you if an overdose happens.

If any overdose occurs, you should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

5. What should I know while receiving MARCAIN?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using MARCAIN.

Driving or using machines

Be careful before you drive or use any machines or tools after you have been given MARCAIN.

You may be drowsy and your reflexes may be slow.

Drinking alcohol

Do not drink alcohol while you are being given MARCAIN.

If you drink alcohol while you are being given MARCAIN your blood pressure may drop, making you feel dizzy and faint.

Looking after this medicine

MARCAIN will be stored by your doctor or pharmacist under the recommended conditions.

MARCAIN in plastic bags or ampoules should be kept in a cool dry place where the temperature stays below 30 °C. MARCAIN with ADRENALINE in glass vials should be kept in a cool dry place where the temperature stays below 25°C.

When to discard your medicine

Any MARCAIN which is not used and which is left in the container will be disposed of in a safe manner by your doctor.

6. Are there any side effects?

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given MARCAIN.

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.

MARCAIN will help relieve pain in most people, but it may have unwanted side-effects.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">nervousnessdizzinessblurred visiona tingling feeling ("pins and needles")ringing in the earsnumbnessfeeling strange (disoriented)nausea (feeling sick), vomiting.	<p>Tell your doctor or nurse if you notice any of these side effects.</p> <p>These are all mild side effects of MARCAIN.</p>

Serious side effects

Serious side effects	What to do
<p>If MARCAIN is given wrongly, or you are very sensitive to it, it sometimes causes:</p> <ul style="list-style-type: none">fitsunconsciousnessbreathing problemslow blood pressureslow heart beatcollapse.	<p>Tell your doctor straight away if you notice any of these serious side effects. You may need urgent medical attention.</p> <p>Serious side effects are rare.</p>

After an epidural injection you may develop a headache or backache which is not always related to the medicine used. This can, on rare occasions, last for some months after the injection is given.

Tell your doctor 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.

7. Product details

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

What MARCAIN injection contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">bupivacaine hydrochloride <p><i>(refer to below description for strength & pack types)</i></p>
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">sodium chloridesodium hydroxide or hydrochloric acid (for pH adjustment)water for injections.

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

What MARCAIN injection looks like

MARCAIN is a clear and colourless sterile solution for injection or infusion, available in different strengths and pack types.

- MARCAIN 0.125% EPIDURAL INFUSION
Contains bupivacaine hydrochloride 1.25 mg/mL. Available in packs of 5 x 200 mL polypropylene bags.
- MARCAIN 0.25% bupivacaine hydrochloride 50 mg/20 mL injection
Contains bupivacaine hydrochloride 2.5 mg/mL. Available in packs of 5 x 20 mL polypropylene ampoules.
- MARCAIN 0.25% EPIDURAL INFUSION
Contains bupivacaine hydrochloride 2.5 mg/mL. Available in packs of 5 x 100 mL polypropylene bags.
- MARCAIN 0.5% bupivacaine hydrochloride 50 mg/10 mL injection

Contains bupivacaine hydrochloride 5.0 mg/mL. Available in packs of 5 x 10 mL and 50 x 10 mL polypropylene ampoules.

- MARCAIN 0.5% bupivacaine hydrochloride 100 mg/20 mL injection

Contains bupivacaine hydrochloride 5.0 mg/mL. Available in packs of 5 x 20 mL polypropylene ampoules.

Australian Registration numbers:

- MARCAIN 0.125% EPIDURAL INFUSION: AUST R 48374
- MARCAIN 0.25% bupivacaine hydrochloride 50 mg/20 mL injection: AUST R 48380
- MARCAIN 0.25% EPIDURAL INFUSION: AUST R 11953
- MARCAIN 0.5% bupivacaine hydrochloride 50 mg/10 mL injection: AUST R 11937
- MARCAIN 0.5% bupivacaine hydrochloride 100 mg/20 mL injection: AUST R 48328.

What MARCAIN with ADRENALINE injection contains

Active ingredients (main ingredients)	<ul style="list-style-type: none">• bupivacaine hydrochloride• adrenaline (epinephrine) <p><i>(refer to below description for strength)</i></p>
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• sodium chloride• hydrochloric acid (for pH adjustment)• sodium metabisulfite• water for injections.
Potential allergens	<ul style="list-style-type: none">• sulfites.

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

What MARCAIN with ADRENALINE injection looks like

MARCAIN with ADRENALINE is a clear and colourless sterile solution for injection, available in different strengths.

- MARCAIN 0.25% with ADRENALINE 1:400,000
Contains bupivacaine hydrochloride 2.5 mg/mL and adrenaline (epinephrine) 2.5 microgram/mL. Available in packs of 5 x 20 mL glass vials.
- MARCAIN 0.5% with ADRENALINE 1:200,000
Contains bupivacaine hydrochloride 5 mg/mL and adrenaline (epinephrine) 5 microgram/mL. Available in packs of 5 x 20 mL glass vials.

Australian Registration numbers:

- MARCAIN 0.25% with ADRENALINE 1:400,000: AUST R 125878

- MARCAIN 0.5% with ADRENALINE 1:200,000: AUST R 48329

Who distributes MARCAIN

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos St
St Leonards NSW 2065
Australia

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