

MARCAIN® and MARCAIN with adrenaline INJECTION

Bupivacaine hydrochloride

Bupivacaine hydrochloride and adrenaline (epinephrine) (as acid tartrate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about MARCAIN. It does not contain all the information that is known about MARCAIN.

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

All medicines have risks and benefits. Your doctor will have weighed the risks of you using MARCAIN against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What MARCAIN is for

MARCAIN 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.

MARCAIN belongs to a group of medicines called local anaesthetics.

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 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.

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

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for uses other than those listed above. Ask your doctor if you want more information.

MARCAIN is not addictive

Before you are given MARCAIN

When you must not be given it

Ask your doctor about the risks and benefits of being given MARCAIN while 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.

MARCAIN will only be used if the solution is clear, the package is undamaged and the use by (expiry) date marked on the pack has not been passed.

It may have no effect at all, or worse, an entirely unexpected effect if you are given MARCAIN after the expiry date.

Before you are given it

You must tell your doctor if:

1. you have any allergies to

- any ingredients listed at the end of this leaflet
- other local anaesthetics e.g. lignocaine
- any other substances

If you have an allergic reaction, you may get a skin rash, hayfever, have difficulty breathing or feel faint.

2. you have any of these 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 take MARCAIN if you have any of these conditions.

Taking other medicines

Tell your doctor if you are taking any other medicines, including

- 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.

These medicines may affect the way MARCAIN works.

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

If you have not told your doctor about any of these things, tell them before you are given any MARCAIN.

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.

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. The last will be the case if you are given an EPIDURAL injection (an injection around the spinal cord) and will result in a feeling of numbness in your lower body.

If you are receiving an EPIDURAL INFUSION it will be injected by

your doctor into the epidural space, near your spinal cord, through a space between vertebrae in your lower back. 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.

The dosage you will be given 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. They will be willing to discuss this decision with you.

Overdose

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.

While you are being given it

Things to be careful of

Be careful driving or operating machinery after you have been given MARCAIN.

You may be drowsy and your reflexes may be slow.

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.

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

Side effects

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

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

All medicines can have 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.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

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

- nervousness
- dizziness
- blurred vision
- a tingling feeling ("pins and needles")
- ringing in the ears
- numbness
- feeling strange (disoriented)
- nausea (feeling sick), vomiting

These are all mild side effects of MARCAIN.

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.

If MARCAIN is given wrongly, or you are very sensitive to it, it sometimes causes

- fits
- unconsciousness
- breathing problems
- low blood pressure
- slow heart beat

- collapse

These are all serious side effects.

You may need urgent medical attention. Serious side effects are rare.

Some people may get other side effects while being given MARCAIN.

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

After using it

Storage

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

MARCAIN in glass should be kept in a cool dry place where the temperature stays below 25°C. MARCAIN in plastic should be kept in a cool dry place where the temperature stays below 30 °C.

Disposal

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

Product description

MARCAIN and MARCAIN WITH ADRENALINE containing solutions are clear and colourless.

Each MARCAIN solution contains Bupivacaine hydrochloride as the active ingredient,

plus,

- Sodium chloride
- Sodium hydroxide or hydrochloric acid for pH adjustment
- Water for injections

Each MARCAIN WITH ADRENALINE solution contains

Bupivacaine hydrochloride and Adrenaline (epinephrine) (as acid tartrate) as the active ingredients, plus,

- Hydrochloric acid
- Sodium chloride
- Sodium metabisulfite (E223)
- Water for Injections

In the USA adrenaline is known as epinephrine.

What is in Marcaïn

MARCAIN 0.125% Infusion

Bupivacaine hydrochloride
1.25mg/mL
PACK SIZES 5 X 100mL
PACK TYPE Polybag®
AUST R 12424

MARCAIN 0.125% Infusion

Bupivacaine hydrochloride
1.25mg/mL
PACK SIZES 5 X 200mL
PACK TYPE Polybag®
AUST R 48374

MARCAIN 0.25%

Bupivacaine hydrochloride
2.5mg/mL
PACK SIZES 5 X 20mL
PACK TYPE Polyamp®
AUST R 48380

MARCAIN 0.25% Infusion

Bupivacaine hydrochloride
2.5mg/mL
PACK SIZES 5 X 100mL
PACK TYPE Polybag®
AUST R 11953

MARCAIN 0.25% with adrenaline 1: 400,000

Bupivacaine hydrochloride
2.5mg/mL
Adrenaline (epinephrine)
2.5microgram/mL (as acid tartrate)
PACK SIZES 5 x 20mL*
PACK TYPE single dose vial
AUST R 125878

MARCAIN 0.375%

Bupivacaine hydrochloride
3.75mg/mL
PACK SIZES 5 x 20mL
PACK TYPE Polyamp®
AUST R 52691

MARCAIN 0.5%

Bupivacaine hydrochloride
5.0mg/mL
PACK SIZES 5 x 10mL and 50 x 10mL
PACK TYPE Polyamp®
AUST R 11937

MARCAIN 0.5%

Bupivacaine hydrochloride
5.0mg/mL
PACK SIZES 5 x 20mL
PACK TYPE Polyamp®
AUST R 48328

MARCAIN 0.5% with adrenaline 1:200,000

Bupivacaine hydrochloride
5.0mg/mL
Adrenaline (epinephrine)
5microgram/mL (as acid tartrate)
PACK SIZES 5 x 20mL*
PACK TYPE single dose vial
AUST R 48329

* contains sodium metabisulfite

Not all presentations are marketed.

Sponsor

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

This leaflet was revised in May 2017.

®Trade Marks herein are the property of the AstraZeneca group