

MARCAIN® 0.5% and MARCAIN SPINAL 0.5% HEAVY INJECTION

Bupivacaine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about Marcain 0.5% and Marcain Spinal 0.5% Heavy. It does not contain all the information that is known about Marcain 0.5% and Marcain Spinal 0.5% Heavy.

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 being given Marcain 0.5% or Marcain Spinal 0.5% Heavy against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What MARCAIN 0.5% and MARCAIN SPINAL 0.5% HEAVY are for

Marcain 0.5% and Marcain Spinal 0.5% Heavy are used to prevent or relieve pain, before surgery of the lower abdomen and lower limbs. They will not put you to sleep.

Marcain 0.5% and Marcain Spinal 0.5% Heavy can also be used to make childbirth less painful.

Marcain 0.5% and Marcain Spinal 0.5% Heavy belong to a group of medicines called spinal local anaesthetics. They are injected into

the spinal fluid where they make the nerves unable to pass messages to the brain.

Depending on the amount used, Marcain 0.5% and Marcain Spinal 0.5% Heavy will either totally stop pain or will cause a partial loss of feeling.

Your doctor will have explained why you are being treated with Marcain 0.5% or Marcain Spinal 0.5% Heavy 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 another use. Ask your doctor if you want more information.

Marcain 0.5% and Marcain Spinal 0.5% Heavy are not addictive.

Before you are given MARCAIN 0.5% or MARCAIN SPINAL 0.5% HEAVY

When you must not have it

Do not use Marcain 0.5% or Marcain Spinal 0.5% Heavy if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

We do not know if it is safe for you to be given it while you are pregnant. They may affect your baby if you take it early in

pregnancy or in the last weeks before your baby is due. However, they can be used during childbirth.

Your baby can take in very small amounts of Marcain 0.5% or Marcain Spinal 0.5% Heavy from breast milk if breastfeeding.

Marcain 0.5% and Marcain Spinal 0.5% Heavy 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.

They may have no effect at all, or worse, an entirely unexpected effect if you are given them 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 eg. lignocaine
- any other substances

If you have an allergic reaction, you may get a skin rash, hay fever or difficulty breathing.

2. you have any of these medical conditions

- problems with your blood pressure or circulation
- blood poisoning
- problems with the clotting of your blood
- nerve or heart problems
- liver or kidney problems
- malignant hyperthermia
- diseases of the brain or spine
- some types of back problems

It may not be safe for you to be given Marcain 0.5% or Marcain Spinal 0.5% Heavy if you have any of these conditions.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy at the chemist, supermarket or health food shop.

These medicines may affect the way Marcain 0.5% or Marcain Spinal 0.5% Heavy work.

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 0.5% or Marcain Spinal 0.5% Heavy.

How MARCAIN 0.5% and MARCAIN SPINAL 0.5% HEAVY are given

Marcain 0.5% or Marcain Spinal 0.5% Heavy will be injected by your doctor into the spinal canal, through a space between the bones in your lower back. This is called a SPINAL injection and it will result in a feeling of numbness in your lower body, in an area that may seem unrelated to the site of injection.

Marcain 0.5% and Marcain Spinal 0.5% Heavy 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 0.5% and Marcain Spinal 0.5% Heavy 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 0.5% or Marcain Spinal 0.5% Heavy will be experienced in the use of spinal local anaesthetics, so it is unlikely that you will be given an overdose.

However, if you are particularly sensitive to Marcain 0.5% or Marcain Spinal 0.5% Heavy, 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 0.5% or Marcain Spinal 0.5% Heavy, equipment will be available to care for 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 0.5% or Marcain Spinal 0.5% Heavy.

You may be drowsy and your reflexes may be slow.

Do not drink alcohol while you are being given Marcain 0.5% or Marcain Spinal 0.5% Heavy.

If you drink alcohol while you are being given Marcain 0.5% or Marcain Spinal 0.5% Heavy 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 0.5% or Marcain Spinal 0.5% Heavy.

Marcain 0.5% and Marcain Spinal 0.5% Heavy will prevent or relieve pain in most people, but they 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 if you notice any of the following and they worry you:

- nervousness
- dizziness
- blurred vision
- drowsiness
- ringing in the ears
- numbness
- feeling strange (disoriented)
- nausea
- vomiting

These are all mild side effects of Marcain 0.5% and Marcain Spinal 0.5% Heavy.

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

If Marcain 0.5% or Marcain Spinal 0.5% Heavy 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

Some people may get other side effects while being given Marcain 0.5% or Marcain Spinal 0.5% Heavy.

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

After using it

Storage

Marcaïn 0.5% or Marcaïn Spinal 0.5% Heavy will be stored by your doctor or pharmacist under the recommended conditions.

It should be kept in a cool dry place where the temperature stays below 25 °C.

Disposal

Any Marcaïn 0.5% or Marcaïn Spinal 0.5% Heavy which is not used, will be disposed of in a safe manner by your doctor or pharmacist.

Product description

Each Marcaïn 0.5% Injection contains bupivacaine hydrochloride 0.5% (5mg/mL) as the active ingredient,

plus

- Sodium chloride
- Hydrochloric acid or sodium hydroxide for pH adjustment
- Water for Injections

Each Marcaïn Spinal 0.5% Heavy Injection contains bupivacaine hydrochloride 0.5% w/v (5mg/ml) as the active ingredient,

plus

- Glucose 8% w/v (80mg/mL)
- Hydrochloric acid or sodium hydroxide for pH adjustment
- Water for Injections

The inclusion of glucose in Marcaïn Spinal 0.5% Heavy means that it will move along your spinal canal with gravity, depending on which way your body is tilted.

Marcaïn 0.5% and Marcaïn Spinal 0.5% Heavy are available as 4mL glass ampoules in Sterile AstraZeneca Theatre Pack™ in packs of 5.

Sponsor

Aspen Pharmacare Australia Pty Ltd

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St Leonards NSW 2065
Australia

Australian Registration Number

MARCAIN 0.5% (SPINAL)
glass ampoules 21016

**MARCAIN SPINAL 0.5%
HEAVY**

glass ampoules 11941

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