

BUPIVADREN

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

Consumer Medicine Information

What is in this leaflet

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

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 Bupivadren 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 Bupivadren is used for

Bupivadren is used to prevent or relieve pain, but it will not put you to sleep.

Bupivadren is also used after surgery to relieve pain. It can also be used to make childbirth less painful.

Bupivadren 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, Bupivadren will either totally stop pain or will cause a partial loss of feeling.

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

Your doctor will have explained why you are being treated with Bupivadren 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.

Bupivadren is not addictive

Before you are given Bupivadren

When you must not take it

Ask your doctor about the risks and benefits of being given Bupivadren 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 Bupivadren from breast

milk if you are breastfeeding, but it is unlikely that the amount available to the baby will do any harm.

Bupivadren 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 Bupivadren 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 Bupivadren 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 Bupivadren 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 Bupivadren.

How Bupivadren is given

Bupivadren 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.

Bupivadren 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 Bupivadren 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 Bupivadren 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 Bupivadren, 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 Bupivadren, equipment will be available to revive you if an overdose happens.

While you are being given Bupivadren

Things to be careful of

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

You may be drowsy and your reflexes may be slow.

Do not drink alcohol while you are being given Bupivadren.

If you drink alcohol while you are being given Bupivadren 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 Bupivadren.

Bupivadren 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 Bupivadren.

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 Bupivadren 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

Bupivadren.

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

After using Bupivadren

Storage

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

Bupivadren should be kept in a cool dry place where the temperature stays below 25°C and should also be protected from light. Do not freeze.

Disposal

Any Bupivadren 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

Bupivadren solution is clear and colourless. It is practically free from visible particles.

Ingredients

Bupivadren solution contains Bupivacaine hydrochloride monohydrate and Adrenaline (epinephrine) acid tartrate as the active ingredients and following inactive ingredients:

- Sodium chloride
- Water for injections
- Sodium metabisulfate

- Sodium citrate dihydrate
- Citric acid

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes (include any that are appropriate).

Bupivadren, Bupivacaine 0.25% with adrenaline (epinephrine) 1:400,000

Bupivacaine hydrochloride (as monohydrate) 2.5mg/mL

Adrenaline (epinephrine) 2.5 microgram/mL

Pack Size 5x 20mL

Pack type single dose vial

AUST R 292526

Bupivadren, Bupivacaine 0.5% with adrenaline (epinephrine) 1:200,000

Bupivacaine hydrochloride (as monohydrate) 5.0mg/mL

Adrenaline (epinephrine) 5.0 microgram/mL

Pack Size 5x 20mL

Pack type single dose vial

AUST R 292528

Not all presentation are marketed

Sponsor

Bupivadren is supplied by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

This leaflet was prepared in April 2020