

BUPIVADREN

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.

1. Why am I using Bupivadren?

Bupivadren contains two active ingredients: adrenalin (epinephrine) and bupivacaine hydrochloride.

Bupivacaine is combined with adrenaline (epinephrine) to make it last longer. Bupivadren belongs to a group of medicines called local anaesthetics.

Bupivadren is used to prevent or relieve pain, including in childbirth and after surgery, but it will not put you to sleep.

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

2. What should I know before I use Bupivadren?

Do not use if you have ever had an allergic reaction to adrenaline (epinephrine) acid tartrate, bupivacaine hydrochloride monohydrate, other local anaesthetics e.g.

lignocaine, or any of the ingredients listed at the end of the CMI.

Do not use if you have severe heart disease, thyrotoxicosis (hyperthyroidism) or blood poisoning.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with Bupivadren 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 do I use Bupivadren?

- Bupivadren is given in a clinical setting by a doctor or nurse.
- 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.

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

5. What should I know while using Bupivadren?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using Bupivadren.• Tell your doctor or nurse immediately if you develop problems with your sight, hearing, get a numb feeling in or around the mouth, feel dizzy, restless, anxious, suddenly depressed, drowsy, feel lightheaded, or have stiff, shaking or twitchy muscles.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Bupivadren affects you.• You may be drowsy and your reflexes may be slow.

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

6. Are there any side effects?

Less serious side effects: nausea or vomiting; lightheaded or dizziness; blurred or double vision; ringing in the ears; a tingling feeling or numbness; sensations of hot or cold; feeling strange, anxious, nervous, restless or euphoric; confusion or agitation; inability to tolerate sound; racing heart; headache; inability to pass urine; muscle weakness, twitching or tremors; numbness of the tongue, difficulty swallowing or slurred speech.

More serious side effects: loss of bladder or bowel control, sexual function, movement of the lower body; unusual burning or stinging pain; fits; breathing problems; low blood pressure; slow heartbeat; unconsciousness or collapse.

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.

BUPIVADREN

Active ingredient(s): *Bupivacaine hydrochloride (as monohydrate) and adrenaline (epinephrine) acid tartrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Bupivadren. **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 Bupivadren.

Where to find information in this leaflet:

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

1. Why am I using Bupivadren?

Bupivadren contains the active ingredients adrenaline (epinephrine), and bupivacaine hydrochloride.

Bupivadren belongs to a group of medicines called local anaesthetics.

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

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.

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.

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.

2. What should I know before I use Bupivadren?

Warnings

Do not use Bupivadren if:

1. you are allergic to adrenaline (epinephrine) acid tartrate, bupivacaine hydrochloride monohydrate, sodium metabisulfite or any of the ingredients listed at the end of this leaflet.
2. Always check the ingredients to make sure you can use this medicine.

3. You are allergic to other local anaesthetics e.g. lignocaine

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

4. you have any of these medical conditions:

- blood poisoning
- severe heart disease
- thyrotoxicosis (hyperthyroidism – where your thyroid gland produces too much hormone), which is not controlled
- cerebral arteriosclerosis

Check with your doctor if you:

Have any other medical conditions including:

- diabetes
- heart, liver or kidney problems
- heart problems, also including problems with blood pressure and circulation
- problems with the clotting of your blood
- epilepsy
- muscle disease or weakness (e.g. myasthenia gravis)
- diseases affecting the brain, spine or nerves
- acidosis (too much acid in the blood)
- hyperkalaemia (too much potassium in your blood)
- hypocalcaemia (low calcium levels in your blood)
- Are pregnant or breastfeeding.

It may not be safe for you to take Bupivadren if you have any of these conditions.



Take any medicines for any other condition.

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?](#)

Experience in children under the age of 12 is limited.

Pregnancy and breastfeeding

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.

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.

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 may interfere with Bupivadren and affect how it works.

Such medicines may include:

- medicines that control your heartbeat or used for heart failure
- medicines used to thin the blood, including aspirin
- low molecular weight heparin or other medicines used to prevent blood clots
- medicines for depression or mental illness
- medicines for allergies
- medicines used to help thyroid function
- beta-blockers, which may be used for a wide range of conditions
- medicines that you buy at the chemist, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Bupivadren.

4. How is Bupivadren used?

How much is given

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

When Bupivadren is given

Bupivadren is given in a clinical setting by a doctor or nurse.

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.

If you use too much Bupivadren

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, restless, anxious, suddenly

depressed, drowsy (sleepy), feel lightheaded, or have stiff, shaking or twitchy muscles. If you experience any of these it is important to tell your doctor or nurse immediately.

Whenever you are given Bupivadren, suitable procedures should be available if you experience signs of being given too much.

Symptoms of an overdose may include the side effects listed in [Section 6 Are there any side effects?](#) but are usually of a more severe nature.

5. What should I know while using Bupivadren?

Things you should do

Remind any doctor or dentist you visit that you are using Bupivadren.

Tell your doctor or nurse immediately if you develop problems with your sight or hearing, get a numb feeling in or around the mouth, feel dizzy, restless, anxious, suddenly depressed, drowsy (sleepy), feel lightheaded, or have stiff, shaking or twitchy muscles.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Bupivadren affects you.

You may be drowsy, have impaired mental function and your reflexes may be slow.

Looking after your medicine

Bupivadren will be stored by in the hospital or clinic under the recommended conditions.

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.

When to discard your medicine (as relevant)

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 nurse.

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 nurse as soon as possible if you do not feel well while you are being given Bupivadren.

Less serious side effects

Less serious side effects	What to do
<p data-bbox="204 432 571 533">Gastrointestinal symptoms:</p> <ul data-bbox="204 568 692 685" style="list-style-type: none"><li data-bbox="204 568 692 622">• nausea (feeling sick)<li data-bbox="204 636 427 685">• vomiting <p data-bbox="204 712 772 813">Sight and senses related symptoms:</p> <ul data-bbox="204 848 772 1413" style="list-style-type: none"><li data-bbox="204 848 772 902">• lightheaded or dizziness<li data-bbox="204 916 751 969">• blurred or double vision<li data-bbox="204 983 635 1037">• ringing in the ears<li data-bbox="204 1050 735 1216">• a tingling feeling ("pins and needles") or numbness<li data-bbox="204 1229 772 1283">• sensations of hot or cold<li data-bbox="204 1296 564 1413">• feeling strange (disoriented) <p data-bbox="204 1440 746 1485">Nervous system related</p> <ul data-bbox="204 1520 778 1995" style="list-style-type: none"><li data-bbox="204 1520 778 1619">• anxiety, nervousness, restlessness or euphoria<li data-bbox="204 1632 708 1686">• confusion or agitation<li data-bbox="204 1700 639 1798">• inability to tolerate sound<li data-bbox="204 1812 778 1995">• numbness of the tongue, difficulty swallowing or slurred speech	<p data-bbox="817 432 1378 651">Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<p>Muscle related</p> <ul style="list-style-type: none"> • muscle weakness, twitching or tremors <p>Heart related</p> <ul style="list-style-type: none"> • racing heart <p>Kidney related</p> <ul style="list-style-type: none"> • inability to pass urine <p>Other</p> <ul style="list-style-type: none"> • headache 	

Serious side effects

Serious side effects	What to do
<p>Nervous system related</p> <ul style="list-style-type: none"> • loss of movement of the lower body • unusual burning or stinging pain <p>Other</p> <ul style="list-style-type: none"> • loss of bladder or bowel control • loss of sexual function 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>If Bupivadren is given wrongly, or you are very sensitive to it, it may sometimes also cause:</p> <ul style="list-style-type: none"> • fits • unconsciousness • breathing problems • low blood pressure • slow heart beat • collapse <p>Symptoms due to epidural use:</p> <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.</p>	

Tell your doctor or pharmacist 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 Bupivadren contains

Active ingredient (main ingredient)	Bupivacaine hydrochloride monohydrate, and Adrenaline (epinephrine) acid tartrate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• Sodium chloride• Water for injections• Sodium metabisulfate• Sodium citrate dihydrate• Citric acid

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

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

What Bupivadren looks like

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

Bupivadren is available in two strengths:

- AUST R 292526 - BUPIVADREN Bupivacaine 0.25% w/v with Adrenaline (epinephrine) 1:400,000 injection solution vial
- AUST R 292528 - BUPIVADREN Bupivacaine 0.5% w/v with Adrenaline (epinephrine) 1:200,000 injection solution vial

Pack Size 5x 20mL

Pack type single dose vial

Who distributes Bupivadren

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

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