

# BUPIVACAINE WITH ADRENALINE PHEBRA 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.

### 1. Why is Bupivacaine with Adrenaline Injection being used ?

Bupivacaine with Adrenaline Injection contains the active ingredients bupivacaine hydrochloride and adrenaline (epinephrine) (as acid tartrate). Bupivacaine with Adrenaline Injection is used to prevent or relieve pain, but it will not put you to sleep. It is also used after surgery to relieve pain and to make childbirth less painful.

For more information, see Section [1. Why is Bupivacaine with Adrenaline Injection being used ?](#) in the full CMI.

### 2. What should I know before Bupivacaine with Adrenaline Injection is used?

Do not use if you have ever had an allergic reaction to Bupivacaine with Adrenaline Injection 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 plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before Bupivacaine with Adrenaline Injection is used?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Bupivacaine with Adrenaline Injection 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 is Bupivacaine with Adrenaline Injection used?

Bupivacaine with Adrenaline Injection will be injected by your doctor into the skin, near a single nerve, or into an area that contains a large number of nerves.

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

### 5. What should I know while Bupivacaine with Adrenaline Injection is being used?

<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>Be careful driving or operating machinery after you have been given Bupivacaine with Adrenaline Injection.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>Do not drink alcohol if your doctor plans to administer Bupivacaine with Adrenaline Injection.</li> </ul>
<b>Looking after the medicine</b>	<ul style="list-style-type: none"> <li>Bupivacaine with Adrenaline Injection should be kept in a cool dry place where the temperature stays below 25°C.</li> </ul>

For more information, see Section [5. What should I know while Bupivacaine with Adrenaline Injection is being used?](#) in the full CMI.

### 6. Are there any side effects?

Bupivacaine with Adrenaline Injection may cause nervousness, dizziness, blurred vision, a tingling feeling (pins and needles), ringing in the ears, numbness, feeling strange (disoriented), nausea (feeling sick), vomiting, seizure, unconsciousness, breathing problems, low blood pressure, slow heartbeat and 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.

# Bupivacaine with Adrenaline Phebra Injection

Active ingredients: *bupivacaine hydrochloride and adrenaline (epinephrine) (as acid tartrate)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Bupivacaine with Adrenaline 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 Bupivacaine with Adrenaline Injection being used.**

Where to find information in this leaflet:

- [1. Why is Bupivacaine with Adrenaline Injection being used?](#)
- [2. What should I know before Bupivacaine with Adrenaline Injection is used?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Bupivacaine with Adrenaline Injection used?](#)
- [5. What should I know while Bupivacaine with Adrenaline Injection is being used?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why is Bupivacaine with Adrenaline Injection being used ?

**Bupivacaine with Adrenaline Injection contains the active ingredients bupivacaine hydrochloride (as monohydrate) and adrenaline (epinephrine) (as acid tartrate).**

Bupivacaine with Adrenaline Injection belongs to a group of medicines known as local anaesthetics.

**Bupivacaine with Adrenaline Injection is used to prevent or relieve pain, but it will not put you to sleep. It is also used after surgery to relieve pain and to make childbirth less painful.**

Depending on the amount used, Bupivacaine with Adrenaline Injection will either totally stop pain or will cause a partial loss of feeling. When injected it makes the nerves nearby unable to pass messages to the brain and will therefore prevent or relieve pain.

Your doctor will have explained why you are being treated with Bupivacaine with Adrenaline Injection and what dose you will be given.

**Follow all the directions and advice given to you by your doctor carefully.**

Your doctor may have prescribed Bupivacaine with Adrenaline Injection for uses other than those listed above.

## 2. What should I know before Bupivacaine with Adrenaline Injection is used?

### Warnings

**Do not use Bupivacaine with Adrenaline Injection if:**

- you are allergic to bupivacaine or adrenaline (epinephrine), other local anaesthetics [e.g. lidocaine (lignocaine)] or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you have or have had:**

- 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
- a disease of the brain or spine
- thyrotoxicosis
- diabetes
- muscle disease or weakness (e.g. myasthenia gravis).
- hyperkalaemia (too much potassium in your blood)
- hypocalcaemia (low calcium levels in your blood)

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

**Ask your doctor about the risks and benefits of being given Bupivacaine with Adrenaline Injection while you are pregnant or breastfeeding.**

Check with your doctor if you are pregnant or intend to become pregnant.

It is not known if it is safe for you to be given Bupivacaine with Adrenaline Injection while you are pregnant. It may affect your baby if you are given early in pregnancy or in the last weeks before your baby is due. However, Bupivacaine with Adrenaline Injection can be used during childbirth.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

If you have not told your doctor about any of the above, tell him/her before you are given Bupivacaine with Adrenaline Injection.

### 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 Bupivacaine with Adrenaline Injection and affect how it works.**

**Such medicines may include:**

- medicines that control your heartbeat, including beta-blockers
- medicines used to thin the blood, including aspirin
- low molecular weight heparin or other medicines used to prevent blood clots
- medicines for depression
- medicines for allergies
- medicines used to help thyroid function
- inhaled anaesthetics
- quinidine used to treat malaria
- oxytocic drugs of ergot type
- 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 Bupivacaine with Adrenaline Injection.**

### 4. How is Bupivacaine with Adrenaline Injection used ?

**How much to use**

- The dosage you will be given will depend on your body size, age and the type of pain relief required. Your doctor will determine the best dose for you.

**If you use too much Bupivacaine with Adrenaline Injection**

Bupivacaine with Adrenaline Injection will be given to you by a doctor and so it is unlikely that you will be given an overdose.

However, if you are particularly sensitive to Bupivacaine with Adrenaline Injection, 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. If you experience any of these it's important to tell your doctor or nurse.

Whenever you are given Bupivacaine with Adrenaline Injection, your doctor will have suitable equipment and procedures in place 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 Bupivacaine with Adrenaline Injection is being used?

**Driving or using machines**

**Be careful driving or operating machinery after you have been given Bupivacaine with Adrenaline Injection.**

Bupivacaine with Adrenaline Injection may cause dizziness, light-headedness or weakness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else dangerous.

**Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Do not drink alcohol if your doctor plans to administer Bupivacaine with Adrenaline Injection.

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

**Looking after your medicine**

- Bupivacaine with Adrenaline Injection will be stored by your doctor or pharmacist under the recommended conditions, out of the reach of children.
- Bupivacaine with Adrenaline Injection should be kept in a cool dry place where the temperature stays below 25°C.

### 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.

### Less serious side effects

Less serious side effects	What to do
<p><b>Ear related:</b></p> <ul style="list-style-type: none"> <li>ringing in the ears</li> </ul> <p><b>Eye related:</b></p> <ul style="list-style-type: none"> <li>blurred vision</li> </ul> <p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>nausea (feeling sick)</li> <li>vomiting</li> </ul> <p><b>Musculoskeletal:</b></p> <ul style="list-style-type: none"> <li>backache</li> <li>numbness</li> <li>muscle weakness, twitching or tremors</li> </ul> <p><b>Nervous system:</b></p> <ul style="list-style-type: none"> <li>a tingling feeling (pins and needles)</li> <li>lightheaded or dizziness</li> <li>feeling strange (disoriented)</li> <li>headache</li> <li>sensations of hot and cold</li> <li>nervousness, anxiety, restlessness or euphoria</li> <li>confusion or agitation</li> <li>numbness of the tongue, difficulty swallowing or slurred speech</li> </ul> <p><b>Heart related:</b></p> <ul style="list-style-type: none"> <li>racing heart</li> </ul> <p><b>Kidney related</b></p> <ul style="list-style-type: none"> <li>inability to pass urine</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Cardiovascular related:</b></p> <ul style="list-style-type: none"> <li>collapse</li> <li>low blood pressure</li> <li>slow heartbeat</li> </ul> <p><b>Nervous system:</b></p> <ul style="list-style-type: none"> <li>seizure</li> <li>unconsciousness</li> <li>loss of movement of the lower body</li> <li>unusual burning or stinging pain</li> </ul> <p><b>Respiratory system:</b></p> <ul style="list-style-type: none"> <li>breathing problems</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>loss of bladder or bowel control</li> <li>loss of sexual function</li> </ul>	<p><b>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.</b></p>

**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](http://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

Bupivacaine with Adrenaline Injection is a prescription medicine and is only administered under a doctor's supervision.

### What Bupivacaine with Adrenaline Injection contains

<b>Active ingredients (main ingredients)</b>	<p>bupivacaine hydrochloride (as monohydrate)</p> <p>adrenaline (epinephrine) (as acid tartrate)</p>
<b>Other ingredients (inactive ingredients)</b>	<p>sodium chloride</p> <p>sodium metabisulfite</p> <p>hydrochloric acid</p> <p>water for injections</p>

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

Bupivacaine with Adrenaline Injection does not contain lactose, sucrose, gluten, tartrazine, alcohol, dyes or any preservatives.

### What Bupivacaine with Adrenaline Injection looks like

Bupivacaine with Adrenaline Injection is a colourless or almost colourless solution in a clear glass vial sealed with a grey rubber stopper and with a flip off tear off seal. It is packaged in a sterile theatre pack.

Bupivacaine with Adrenaline Injection is available in two strengths:

- BUPIVACAINE 0.5% WITH ADRENALINE 1:200,000 PHEBRA solution for injection vial - AUST R 373819
- BUPIVACAINE 0.25% WITH ADRENALINE 1:400,000 PHEBRA solution for injection vial - AUST R 408186

## **Who distributes Bupivacaine with Adrenaline Injection**

Bupivacaine with Adrenaline Injection is manufactured and supplied in Australia by:

Phebra Pty Ltd  
19 Orion Road,  
Lane Cove West,  
NSW 2066, Australia.  
Telephone: 1800 720 020

This leaflet was prepared in January 2024.

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