BUPIVACAINE INJECTION / BUPIVACAINE INJECTION BP

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 being given Bupivacaine Injection?

Bupivacaine Injection contains the active ingredient bupivacaine hydrochloride (as monohydrate). Bupivacaine Injection is used to prevent or relieve pain, but it will not put you to sleep.

For more information, see Section 1. Why am I being given Bupivacaine Injection? in the full CMI.

2. What should I know before I am given Bupivacaine Injection?

Do not use if you have ever had an allergic reaction to bupivacaine 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 I am given Bupivacaine Injection? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Bupivacaine 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 Bupivacaine Injection is given?

- It is given by injection into the skin, near a single nerve, or into an area which contains a large number of nerves.
- Your doctor will decide what dose, how often and how long you will receive it. This depends on the type of pain relief required, your condition and other factors.

More instructions can be found in Section 4. How Bupivacaine Injection is given? in the full CMI.

5. What should I know while receiving Bupivacaine Injection?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Bupivacaine Injection.
Driving or using machines	• Be careful before you drive or use any machines or tools after you have been given Bupivacaine Injection. You may be drowsy and feel light headed. Your reflexes may be made slower and you may feel nauseous.
Looking after your medicine	• Bupivacaine Injection will be stored by your doctor or pharmacist under the recommended conditions.

For more information, see Section 5. What should I know while using Bupivacaine Injection? in the full CMI.

6. Are there any side effects?

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

Some of the side effects may include nervousness, agitation, dizziness, ringing in the ears, blurred vision, numbness, disorientation (feeling strange), nausea, vomiting, difficulty swallowing, slurred speech, shakes (tremor), tingling sensation (pins and needles).

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 INJECTION / BUPIVACAINE INJECTION BP

Active ingredient(s): *bupivacaine hydrochloride monohydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Bupivacaine 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 using Bupivacaine Injection.

Where to find information in this leaflet:

1. Why am I being given Bupivacaine Injection?
2. What should I know before I am given Bupivacaine Injection?
3. What if I am taking other medicines?
4. How Bupivacaine Injection is given?
5. What should I know while using Bupivacaine Injection?
6. Are there any side effects?
7. Product details

1. Why am I being given Bupivacaine Injection?

Bupivacaine Injection contains the active ingredient bupivacaine hydrochloride monohydrate.
Bupivacaine Injection belongs to a group of medicines known as local anaesthetics.

This medicine is used to prevent or relieve pain, but it will not put you to sleep. Bupivacaine Injection is used during or after surgery to relieve pain.

It is injected into the body where it will either totally stop pain or will cause partial loss of feeling (numbness), depending on the amount used.

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

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I am given Bupivacaine Injection?

Warnings

You must not be given Bupivacaine Injection if:

- you are allergic to bupivacaine or any of the ingredients listed at the end of this leaflet.
- you are allergic to other local anaesthetics e.g. lidocaine (lignocaine).

  Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.

  Always check the ingredients to make sure you can use this medicine.
- you have an infection or swelling (redness) where the injection will be given.
- you have uncorrected low blood pressure.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have or have had any of the following medical conditions:
  - problems with your blood pressure or circulation (especially low blood pressure)

- problems with clotting of your blood
- blood poisoning
- acidosis, or too much acid in the blood
- diseases of the brain, spine or nerves
- muscle disease or weakness such as myasthenia gravis
- kidney, liver, heart, or thyroid problems
- epilepsy.

It may not be safe for you to be given Bupivacaine Injection 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?

Pregnancy and 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 receive bupivacaine while you are pregnant. It may affect your baby if you receive it early in pregnancy or in the last weeks before your baby is due. However, bupivacaine may be used during childbirth. Your doctor will discuss with you the benefits and risks of being given it during pregnancy.

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

Your baby can absorb bupivacaine in very small amounts from breast milk if you are breastfeeding. Your doctor will discuss with you the benefits and risks of being given it whilst you are breastfeeding.

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 and Bupivacaine Injection may interfere with each other. These include:

- medicines used to help control your heart beat, such as mexiletine and amiodarone
- medicines to help prevent blood clots such as heparin, low molecular weight heparin; non-steroidal anti-inflammatory drugs such as aspirin or ibuprofen; warfarin; and other medicines that can slow blood clotting.

Your doctor will advise you about continuing to take other medicines while you are receiving Bupivacaine Injection.

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 Injection.

4. How Bupivacaine Injection is given?

How much is given

Your doctor will decide what dose, how often and how long you will receive it. This depends on the type of pain relief required, your condition and other factors, such as your weight, age, how well your liver and kidneys are working, and whether or not other medicines are being given at the same time.

How it is given

Bupivacaine Injection must only be given by a doctor.

It is given by injection into the skin, near a single nerve, or into an area which contains a large number of nerves (e.g. if you are given an epidural injection which is an injection around the spinal cord). This causes an area of numbness at 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 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.

Bupivacaine Injection should not be injected directly into the blood.

If you are given too much Bupivacaine Injection

This rarely happens as Bupivacaine Injection is administered under the care of an experienced anaesthetist. Your condition will be carefully monitored following administration of bupivacaine.

However, if you are given too much bupivacaine, you may experience some of the effects listed under "Section 6. Are there any side effects?" below. Some side effects such as unconsciousness, low blood pressure and collapse will be monitored and detected by your doctor or nurse if it occurs.

Whenever you are given Bupivacaine Injection, equipment is available to treat you if you experience severe side effects.

If you think you have been given too much Bupivacaine Injection or if you experience severe side effects, tell your doctor or nurse immediately.

5. What should I know while using Bupivacaine Injection?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Bupivacaine Injection.

Driving or using machines

Be careful before you drive or use any machines or tools after you have been given Bupivacaine Injection.

You may be drowsy and feel light headed. Your reflexes may be made slower and you may feel nauseous.

Looking after your medicine

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

Getting rid of any unwanted medicine

Any Bupivacaine Injection which is not used will be disposed of in a safe manner by your doctor or pharmacist.

Bupivacaine Injection is for single use only.

6. Are there any side effects?

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

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 nurse if you have any further questions about side effects.

Side effects

Side effects	What to do
• nervousness, agitation • dizziness • ringing in the ears • blurred vision • numbness • disorientation (feeling strange) • nausea • vomiting • difficulty swallowing, slurred speech • shakes (tremor), tingling sensation (pins and needles). These are usually mild side effects and should only last a short time. After an epidural injection of bupivacaine you may develop a headache or backache which is not always related to the	**Speak to your doctor or nurse if you notice any of these side effects.**

Side effects	What to do
medicine used. This may last for some months after the injection was given, although this is rare.	

Serious side effects

Serious side effects	What to do
• fits • difficulty breathing • severe dizziness with slow or irregular heart beat • joint pain, stiffness or loss of motion. If Bupivacaine Injection is given wrongly, or you have a known sensitivity to it, it may cause the above side effects.	**Tell your doctor or nurse straight away if you notice any of these serious side effects. You may need urgent medical attention.** **Serious side effects are rare.**

Tell your doctor or nurse 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.

7. Product details

This medicine is only available with a doctor's prescription.

What Bupivacaine Injection contains

Active ingredient **(main ingredient)**	bupivacaine hydrochloride (as monohydrate)
Other ingredients **(inactive ingredients)**	• Sodium Chloride • Hydrochloric acid • Sodium hydroxide • Water for Injections.

This medicine does not contain a preservative.

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

What Bupivacaine Injection looks like

Bupivacaine Injection is a clear, colourless solution, available in different strengths and pack types:

- Bupivacaine Injection BP 0.25% (sterile) 50 mg in 20 mL Glass Theatre Vial: AUST R 11314
- Bupivacaine Injection BP 0.5% (sterile) 100 mg in 20 mL Glass Theatre Vial: AUST R 12725
- Bupivacaine Injection BP 0.5% (sterile) 50 mg in 10 mL Steriluer® or Steriamp® Plastic Ampoule: AUST R 11312
- Bupivacaine Injection 0.5% (sterile) 50 mg in 10 mL Glass Vial: AUST R 527497.

Who distributes Bupivacaine Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedical.com.au

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