

BUPIVACAINE INJECTION

Bupivacaine hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Bupivacaine Injection.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Bupivacaine Injection against the benefits this medicine is expected to have for you.

This medicine is likely to be used while you are at the clinic or in hospital. If possible, please read this leaflet carefully before this medicine is given to you. In some cases this leaflet may be given to you after the medicine has been used.

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

Keep this leaflet.

You may need to read it again.

What Bupivacaine Injection is used for

Bupivacaine 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 can also be used to make childbirth less painful.

Bupivacaine Injection belongs to a group of medicines known as local anaesthetics. 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 and what dose you will be given.

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

They may differ from the information contained in this leaflet.

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.

This product is available only on a doctor's prescription.

Before you are given Bupivacaine Injection

When you must not be given it:

Do not use Bupivacaine Injection if you have an allergy to:

- any medicine containing bupivacaine or other local anaesthetics e.g. lignocaine
- any of the ingredients listed at the end of this leaflet.

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.

You should not be given Bupivacaine Injection if:

- you have an infection or swelling (redness) where the injection will be given
- you have uncorrected low blood pressure.

If you are not sure whether any of these apply to you, check with your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell 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,

Tell your doctor if you are breastfeeding or plan to breast feed.

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.

Tell your doctor if you have or have had any medical conditions, especially the following:

- problems with your blood pressure or circulation (especially low blood pressure)
- problems with clotting of your blood
- blood poisoning
- 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.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and bupivacaine may interfere with each other. These include:

- medicines used to help control your heart beat, such as mexiletine
- medicines to help prevent blood clots such as heparin.

These medicines may affect the way bupivacaine works or be affected by bupivacaine. You may need different amounts of your medicine, or you may need to take a different medicine.

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

If you have not told your doctor about any of these things, tell them before you are given any bupivacaine.

How Bupivacaine Injection is given

How it is given

Bupivacaine Injection must only be given by a doctor or nurse.

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.

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.

If you are given too much (overdose)

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 "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.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with bupivacaine.

Like other medicines, bupivacaine can cause some side effects. If they occur, most are likely to be minor or temporary. However, some may be serious and need medical attention.

Ask your doctor or nurse to answer any questions that you may have.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor or nurse if you notice any of the following:

- 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 medicine used. This may last for some months after the injection was given, although this is rare.

Tell your doctor or nurse immediately if notice any of the following:

- 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 are very sensitive to it, it may cause the above side effects.

These are all serious side effects. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above, may occur in some patients. If you notice any other effects, check with your doctor. Some side effects may only be detected by your doctor.

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

After being given Bupivacaine Injection

Be careful driving or operating machinery 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.

Be careful when drinking alcohol following injection with bupivacaine.

It may cause your blood pressure to drop and cause you to feel dizzy and faint.

Disposal

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.

Product Description

What it looks like

Bupivacaine Injection is a clear, colourless solution in either a 20mL glass theatre vial or a plastic 10mL Steriamp® or Steriluer® ampoule.

Ingredients

Bupivacaine Injection contains Bupivacaine Hydrochloride BP (0.25% or 0.5%),

It also contains:

- Sodium Chloride
- Water for Injections .

This medicine does not contain a preservative.

Supplier

Bupivacaine Injection is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114 Australia

Toll Free number: 1800 675 229

Australian registration numbers

Bupivacaine Injection BP 0.25% (sterile) 50mg in 20mL Theatre Vial: AUST R 11314

Bupivacaine Injection BP 0.5% (sterile) 100mg in 20mL Theatre Vial: AUST R 12725

Bupivacaine Injection BP 0.5% (sterile) 50mg in 10mL Steriluer® Ampoule: AUST R 11312

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