

PACKAGE LEAFLET: INFORMATION FOR THE USER

Bupivacaine Hydrochloride 0.25% w/v Solution for Injection and Bupivacaine Hydrochloride 0.5% w/v Solution for Injection

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU ARE GIVEN THIS MEDICINE BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor, pharmacist or nurse.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Bupivacaine Hydrochloride 0.25%w/v solution for Injection and 0.5% w/v solution for injection. It will be referred to as Bupivacaine Injection for ease hereafter.

What is in this leaflet:

1. What Bupivacaine Injection is and what it is used for
2. What you need to know before you take Bupivacaine Injection
3. How to take Bupivacaine Injection
4. Possible side effects
5. How to store Bupivacaine Injection
6. Contents of the pack and other information

1. WHAT BUPIVACAINE INJECTION IS AND WHAT IT IS USED FOR

Bupivacaine Hydrochloride is a local anaesthetic; it produces loss of feeling or sensation that is confined to one part of the body. Bupivacaine belongs to a group of medicines called amide type local anaesthetics.

Bupivacaine Injection is used to numb (anaesthetise) parts of the body. It is used to stop pain happening or to provide pain relief. It can be used to:

- numb parts of the body during surgery in adults and children above 12 years -
- relieve pain in adults, infants and children above 1 year of age

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BUPIVACAINE INJECTION

Do not take Bupivacaine Injection if:

You are allergic (hypersensitive) to bupivacaine hydrochloride or any of the other ingredients of Bupivacaine Injection

(see Section 6: Further information).

- you are allergic to any other local anaesthetics of the same class (such as lidocaine or ropivacaine).
- you have a skin infection near to where the injection will be given.

Warnings and precautions.

Talk to your doctor or pharmacist or nurse before taking Bupivacaine Injection :

- If you have heart, liver or kidney problems.

This is because your doctor may need to adjust the dose of Bupivacaine Injection •

If you have epilepsy.

- If you have been told that you have decreased volume of blood (hypovolaemia).
- you have accumulation of fluid around the lungs
- you are elderly or in poor general health

- you are in the late stages of pregnancy
- you suffer from blood poisoning (septicaemia).
- In children aged less than 12 years as some injections of Bupivacaine Injection in order to numb parts of the body during surgery are not established in younger children. The use of Bupivacaine Injection is not established in children less than 1 year of age. If you are not sure if any of the above apply to you, talk to your doctor before you are given Bupivacaine Injection.

Other medicines and Bupivacaine Injection

. Tell your doctor or pharmacist if you are taking using, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Bupivacaine Injection can affect the way some medicines work and some medicines can have an effect on Bupivacaine Injection.

In particular, tell your doctor if you are taking any of the following medicines:

- Medicines used to treat an uneven heart beat (arrhythmia) such as lidocaine, mexiletine or amiodarone.

Pregnancy, breast feeding and fertility:

Before you are given Bupivacaine Injection tell your doctor if you are pregnant, planning to get pregnant, or if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding..

Driving and using heavy machines:

This medicine may make you feel sleepy and affect the speed of your reactions. After you have been given this medicine, you should not drive or use tools or machines until the next day. In general it is wise to ask your doctor whether it is safe to drive.

Bupivacaine Injection contains Sodium:

This medicine contains less than 1 mmol sodium (23 mg) per dosage, that is to say essentially 'sodium-free'.

3. HOW TO TAKE BUPIVACAINE INJECTION

Bupivacaine Injection will be given to you by a doctor. Your doctor will know the correct way to give you this medicine.

The dose that your doctor gives you will depend on the type of pain relief that you need and the part of your body that the medicine will be injected into. It will also depend on your body size, age, and physical condition. Usually one dose will last long enough but more doses may be given if the surgery takes a long time.

Bupivacaine Injection will be given to you as an injection or infusion. The part of the body where you are injected will depend on why you are being given Bupivacaine Injection. Your doctor will give you Bupivacaine Injection in one of the following places:

- Near to the part of the body that needs to be numbed
- In an area away from the part of the body that needs to be numbed. This is the case if you are given an epidural injection (an injection around the spinal cord).

When Bupivacaine Injection is injected into the body in one of these ways, it stops the nerves from being able to pass pain messages to the brain. It will slowly wear off when the medical procedure is over.

Use in children and adolescents

Depending on the type of required analgesia Bupivacaine Injection is injected slowly either into the epidural space (part of the spine) or other parts of the body by an anaesthesiologist experienced in paediatric anaesthetic techniques. Dosage depends on the age and weight of the patient and will be determined by the anaesthesiologist.

If you have been given too much Bupivacaine Injection

Serious side effects from getting too much Bupivacaine Injection are unlikely. They need special treatment and the doctor treating you is trained to deal with these situations. The first signs of being given too much Bupivacaine Injection are usually as follows:

- Feeling dizzy or light-headed
- Numbness of the lips and around the mouth
- Numbness of the tongue
- Hearing problems
- Problems with your sight (vision).

To reduce the risk of serious side effects, your doctor will stop giving you Bupivacaine injection as soon as these signs appear. This means that if any of these happen to you, or you think you have received too much Bupivacaine Injection, **tell your doctor immediately.**

More serious side effects from being given too much Bupivacaine Injection include twitching of your muscles, fits (seizures), being sick (vomiting) and loss of consciousness.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

Other possible side effects:

Very common (affects more than 1 in 10 people)

- Low blood pressure. This might make you feel dizzy or light-headed.
- Feeling sick (nausea).

Common (affects less than 1 in 10 people)

- Feeling dizzy
- Being sick (vomiting)
- Pins and needles
- High blood pressure (hypertension)
- Slow heart beat
- Problems passing urine.

Uncommon (affects less than 1 in 100 people)

- Feeling light-headed
- Fits (seizures)
- Numbness of the tongue or around mouth
- Abnormal sensation of the skin

- Ringing in the ears or being sensitive to sound
- Difficulty in speaking
- Blurred sight or double vision
- Loss of consciousness
- Shaking (tremors).
- Twitching of your muscles

Rare (affects less than 1 in 1,000 people)

- Nerve damage that may cause changes in sensation or muscles weakness (neuropathy). This may include

peripheral nerve damage

- A condition called arachnoiditis (inflammation of the membrane that surrounds the spinal cord). The signs include a stinging or burning pain in the lower back or legs and tingling, numbness or weakness in the legs
- Spinal cord injury (paraplegia)
- Weak or paralysed legs
- Double vision
- Uneven heart beat or stopped heart beat. This could be life threatening
- Slowed or stopped breathing or stopped heart beat. This could be life-threatening.
- Slowed or stopped breathing or stopped heart beat. This could be life-threatening.

Possible side effects seen with other local anaesthetics which might also be caused by Bupivacaine Injection include:

- Problems with your liver enzymes. This may happen if you have long-term treatment with this medicine
- Collection of pus in the spinal cord
- Loss of sensation
- Deficiency in the amount of oxygen reaching body tissues (hypoxia)
- More than normal level of carbon dioxide in blood (hypercarbia)
- Increased acidity in the blood (acidosis)
- Increased potassium levels in the blood (hyperkalemia)
- Low levels of calcium in the blood (hypocalcaemia)
- Damaged nerves. Rarely this may cause permanent problems.
- Drooping of the upper eyelid, sunk in eye, flushing of the face (Horner's syndrome) are more commonly experienced in pregnant women
- Blindness which is not permanent or problems with muscles of the eyes that are long-lasting. This may happen with some injections given around the eyes. **Additional side effects in children and adolescents:**
- Adverse drug reactions in children are similar to those in adults.

If you notice any of the effects mentioned, inform your doctor as soon as possible.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BUPIVACAINE INJECTION

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and ampoule label after 'Exp.'. The expiry date refers to the last day of that month.

Keep the ampoule in the outer carton in order to protect from light. Do not store above 25°C.

For single use only.

This medicine should not be mixed with any other drugs unless compatibility is known.

The solution must not be stored in contact with metals e.g. needles or metal parts of syringes, as dissolved metal ions may cause swelling at the site of the injection.

Once the ampoule has been opened it should be used immediately. If only part of an ampoule is used, the remaining solution should be discarded.

The solution should not be used if it is discoloured in any way.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Bupivacaine Injection contains:

The active substance is anhydrous bupivacaine hydrochloride present as bupivacaine hydrochloride. bupivacaine injection 0.25% w/v: Each 10ml ampoule contains bupivacaine hydrochloride equivalent to 25mg of anhydrous bupivacaine hydrochloride (2.5mg in 1ml).

Bupivacaine Injection 0.5% w/v: Each 10ml ampoule contains bupivacaine hydrochloride equivalent to 50mg of anhydrous bupivacaine hydrochloride (5mg in 1ml).

Bupivacaine Injection 0.25% w/v contains 1.47 mmol (or 33.8 mg) sodium per 10ml ampoule.

Bupivacaine Injection 0.5% w/v contains 1.40 mmol (or 32.3 mg) sodium per 10ml ampoule. This is to be taken into consideration by patients on a controlled sodium diet.

The other ingredients are sodium chloride and sodium hydroxide in water for injections.

What Bupivacaine Injection looks like and contents of pack:

Bupivacaine Injection is a colourless or almost colourless, aqueous, sterile solution for injection and is available in two strengths:

Bupivacaine Injection BP 0.25% w/v, Solution for Injection: Each 10ml (1ml) glass ampoule contains Bupivacaine Hydrochloride equivalent to 25mg (2.5mg) of Anhydrous Bupivacaine Hydrochloride.

Bupivacaine Injection BP 0.5% w/v, Solution for Injection: Each 10ml (1ml) glass ampoule contains Bupivacaine Hydrochloride equivalent to 50mg (5mg) of Anhydrous Bupivacaine Hydrochloride. Pack size: 10 ampoules may be packaged together in cartons or 10 ampoules may be individually sterile wrapped and packed in cartons or 10 ampoules may be packed in individual sterile nonreclosable lidded trays.

Not all pack sizes may be marketed

Marketing authorisation holder:

Mercury Pharmaceuticals (Ireland) Ltd, 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer:

B. Braun Melsungen AG, Mistelweg 2, 12357, Berlin, Germany.

This leaflet was last revised in September 2019.