



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
BUPIVACAINE INJECTION
Bupivacaine Hydrochloride 5mg/ml

Read this leaflet carefully before you start taking this medicine.

- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

1. What Bupivacaine Injection is and what it is used for
2. What you need to know before you use Bupivacaine Injection
3. How to use 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 confined to one part of the body (local anaesthesia). Bupivacaine belongs to a group of medicines called amide-type local anaesthetics

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 USE BUPIVACAINE INJECTION

Do not take Bupivacaine hydrochloride if:

- You are allergic (hypersensitive) to bupivacaine hydrochloride or any of the other ingredients
- 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.

Take special care with Bupivacaine Injection

Check with your doctor 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 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 by bacteria (septicaemia).
- In children aged less than 12 years.



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Taking other medicines

Please tell your doctor if you are taking, or have recently taken, 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 influence Bupivacaine Injection.

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 and breast feeding:

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.

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:

- Close 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



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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.

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. These effects are normally mild or moderate and often disappear after a short time.

Other possible side effects:

Very common (affects more than 1 in 10 people)

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

Common (affects less than 1 in 10 people)

- Feeling dizzy
- 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 the mouth
- Abnormal sensation of the skin around the mouth
- Ringing in the ears or being sensitive to sound



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- Difficulty in speaking
- Blurred sight or double vision
- Loss of consciousness
- 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 heartbeat (arrhythmias). This could be life-threatening.
- Slowed or stopped breathing or stopped heartbeat. This could be life-threatening.

Possible side effects seen with other local anaesthetics which may 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.
- Blindness which is not permanent or problems with the muscles of the eyes that are long-lasting. This may happen with some injections given around the eyes.
- Drooping of the upper eyelid, sunk in eye or flushing on the affected side of the face (Horner' syndrome) are most commonly experienced in pregnant women.

Additional side effects in children and adolescents

Adverse drug reactions in children are like those in adults.

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 effect, talk to your doctor, pharmacist or nurse. This includes any



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possible side effect not listed in this leaflet.

5. HOW TO STORE BUPIVACAINE INJECTION

- Keep this medicine out of the sight and reach of children.
- Store below 30°C
- Do not use Bupivacaine Injection after the expiry date which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION.

What BUPIVACAINE INJECTION contains

Each ml of Bupivacaine Injection contains 5mg of Bupivacaine Hydrochloride.

What BUPIVACAINE INJECTION looks like and contents of the pack

Clear transparent liquid in 10 x 4ml glass ampoules packed in an inner carton

SUPPLIER AND MANUFACTURER

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