

Package leaflet: Information for the user

Bupivacaine Hydrochloride 0.25% w/v solution for injection **Bupivacaine Hydrochloride 0.5% w/v solution for injection**

bupivacaine hydrochloride

Read all of this leaflet carefully before this medicine is given to you 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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Bupivacaine solution for injection is and what it is used for

Bupivacaine contains a medicine called bupivacaine hydrochloride. It belongs to a group of medicines called local anaesthetics.

Bupivacaine 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 Bupivacaine solution for injection is given to you

You must not be given bupivacaine:

- If you are allergic to bupivacaine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to any other local anaesthetics of the same class (such as lidocaine or ropivacaine).
- If you have a skin infection near to where the injection will be given.
- If you have something called cardiogenic shock (a condition where the heart is unable to supply enough blood to the body).
- If you have something called hypovolaemic shock (very low blood pressure leading to collapse).
- If you have problems with clotting of your blood.
- If you have diseases of the brain or spine such as meningitis, polio or spondylitis.
- If you have a severe headache caused by bleeding inside the head (intracranial haemorrhage).
- If you have problems with your spinal cord due to anaemia.
- If you have blood poisoning (septicaemia).
- If you have had a recent trauma, tuberculosis or tumours of the spine.

You must not be given bupivacaine if any of the above apply to you. If you are not sure, talk to your doctor or nurse before you are given bupivacaine.

Warnings and precautions

Talk to your doctor or nurse before having bupivacaine:

- If you have heart, kidney or liver problems. This is because your doctor may need to adjust the dose of bupivacaine. Problems with your liver enzymes. This may happen if you have long-term treatment with this medicine.
- If you have a swollen stomach due to more fluid than normal.
- If you have a stomach tumour.
- If you have been told that you have decreased volume of blood (hypovolaemia).
- If you have fluid in your lungs.

Children

- In children aged less than 12 years as some injections of bupivacaine in order to numb parts of the body during surgery are not established in younger children. The use of bupivacaine 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 or nurse before you are given bupivacaine.

Other medicines and Bupivacaine solution for injection

Tell your doctor if you are taking, 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 can affect the way some medicines work and some medicines can have an effect on bupivacaine.

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.
- Medicines used to stop blood clots (anti-coagulants).

Your doctor needs to know about these medicines to be able to work out the correct dose of bupivacaine for you.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think that you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

Bupivacaine may make you feel sleepy and affect the speed of your reactions. After you have been given bupivacaine, you should not drive or use tools or machines until the next day.

Bupivacaine solution for injection contains sodium

Bupivacaine solution for injection contains up to 3.15 milligrams (mg) of sodium in each millilitre (ml), equivalent to 31.4 mg per 10 ml ampoule. Your doctor will take this into account if you are on a sodium controlled diet.

3. How Bupivacaine solution for injection is given to you

Bupivacaine 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 will be given to you as an injection. The part of the body where you are injected will depend on why you are being given bupivacaine. Your doctor will give you bupivacaine 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 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.

If you have been given too much Bupivacaine solution for injection

Serious side effects from getting too much bupivacaine 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 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 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, **tell your doctor immediately**.

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

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

4. Possible side effects

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

Severe allergic reactions (rare, may affect up to 1 in 1,000 people)

If you have a severe allergic reaction, **tell your doctor immediately**. The signs may include sudden onset of:

- Swelling of your face, lips, tongue or throat. This may make it difficult to swallow.
- Severe or sudden swelling of your hands, feet and ankles.
- Difficulty breathing.
- Severe itching of the skin (with raised lumps).

Other possible side effects:

Very common (may affect more than 1 in 10 people)

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

Common (may affect up to 1 in 10 people)

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

Uncommon (may affect up to 1 in 100 people)

- Feeling light-headed.
- Fits (seizures).
- Numbness of the tongue or around the mouth.
- Ringing in the ears or being sensitive to sound.

- Difficulty speaking.
- Blurred sight (vision).
- Loss of consciousness.
- Shaking (tremors).
- Twitching of your muscles.

Rare (may affect up to 1 in 1,000 people)

- Double vision.
- Nerve damage that may cause changes in sensation or muscle 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.
- Weak or paralysed legs.
- Uneven heart beat (arrhythmias). 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 include:

- Problems with your liver enzymes. This may happen if you have long-term treatment with this medicine.
- 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.

Do not be concerned by this list of possible side effects. You may not get any of them.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bupivacaine solution for injection

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the container after EXP. The expiry date refers to the last day of that month.
- Store below 30°C. Do not freeze.
- Your doctor or the hospital will normally store bupivacaine and they are responsible for the quality of the product when it has been opened if it is not used immediately. They are also responsible for disposing of any unused bupivacaine correctly.

6. Contents of the pack and other information

What Bupivacaine solution for injection contains

The active ingredient is bupivacaine hydrochloride. Bupivacaine comes in two strengths: 2.5 mg or 5 mg of bupivacaine hydrochloride per ml of solution.

The other ingredients are sodium chloride, sodium hydroxide, hydrochloric acid and water for injections.

What Bupivacaine solution for injection looks like and contents of the pack

Bupivacaine is a solution for injection. It comes in 10 ml or 20 ml plastic ampoules in cartons of 5 or 10. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisations for Bupivacaine solution for injection 0.25% and 0.5% are held by Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland
Tel: +44 (0)1 748 828 391

Bupivacaine solution for injection 0.25% and 0.5% is manufactured by AstraZeneca AB, Forskargatan 18, 151 36 Södertälje, Sweden.

Or

Bupivacaine solution for injection 0.5% is manufactured by ASPEN Notre Dame de Bondeville, 1 Rue de l'Abbaye, 76960 Notre-Dame-de-Bondeville, France

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name number	Reference
Bupivacaine Hydrochloride 0.25% w/v solution for injection 39699/0078	
Bupivacaine Hydrochloride 0.5% w/v solution for injection 39699/0079	

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in August 2023.