

Package leaflet: Information for the patient
Bupivacaine Hydrochloride 0.1% w/v Solution for Infusion
Bupivacaine Hydrochloride 0.125% w/v Solution for Infusion
bupivacaine hydrochloride

Read all of this leaflet carefully before you start using 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.
- If you get any side effects, talk to your doctor, 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 0.1% w/v Solution for Infusion or Bupivacaine Hydrochloride 0.125% w/v Solution for Infusion. It will be referred to as Bupivacaine Infusion Solution for ease hereafter.

What is in this leaflet:

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

1. What Bupivacaine Infusion Solution is and what it is used for

Bupivacaine Infusion Solution contains a medicine called bupivacaine hydrochloride. It belongs to a group of medicines called local anaesthetics. Bupivacaine produces loss of feeling or sensation that is confined to one part of the body.

Bupivacaine Hydrochloride Infusion Solution may be used to prevent or give prolonged relief of pain when injected around the spinal cord, e.g. as an epidural in labour or after a surgical operation.

2. What you need to know before Bupivacaine Infusion Solution is given to you

You must not be given this medicine if you:

- know you are allergic to bupivacaine or to any of the other ingredients (see section 6 of this leaflet)
- are allergic to any other local anaesthetics of the same class (such as lidocaine or ropivacaine).
- are to be injected in a vein of the hands or legs (Bier's block).

You should not be given this medicine as an epidural if you:

- have an infection of the skin with pus at or near the site to be injected
- have inadequate circulation of blood to the heart, sudden loss of blood or weakness of the heart that causes low blood pressure, a weak rapid pulse, sweating and confusion
- have problems with the clotting of your blood or are taking any anticoagulant drugs that thin the blood
- are suffering from any infection, disease or tumour of the brain or spinal cord
- have bleeding inside the head (intracranial haemorrhage)
- have incomplete development of spine (Spina bifida)
- have an abnormal connection between veins and arteries (AV malformation)

- have increased pressure within the brain.

Talk to your doctor or nurse if one of these applies to you before you are given this medicine.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before you are given this medicine, if you:

- suffer from any liver, kidney problems
- suffer from any heart problem, particularly if it affects the heart rate
- suffer from severe shock or low blood pressure
- have breathlessness or restriction to breathing from fluid or a large tumour in the abdomen
- have accumulation of fluid around the lungs
- have a decrease in the amount of fluid circulating in your body causing symptoms such as sweating, mental confusion, dizziness or fainting (for example, due to dehydration or severe blood loss)
- are elderly (senile) or in poor health
- have high blood pressure during pregnancy
- have problems with the circulation of blood to the brain
- have excess fluid in the womb during pregnancy (hydramnios)
- have a tumour of the ovary or the womb
- have accumulation of excess fat in your body
- are in the late stages of pregnancy
- suffer from blood poisoning (septicaemia).

Children

The use of Bupivacaine Infusion Solution in children less than 1 year of age is not established. If your child is aged over 1 and up to 12 years old your doctor will explain how the medicine can be given since some use of this medicine in this age group have not been established in certain procedures.

Other medicines and Bupivacaine Infusion Solution:

Tell your doctor or nurse before you are given this medicine if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

This is because Bupivacaine Infusion Solution can affect how some medicines work and different medicines can affect how Bupivacaine Infusion Solution works. In particular, tell your doctor if you are taking any of the following:

- medicines used to regulate the heartbeat such as lidocaine, amiodarone, mexiletine.
- medicines used to reduce the clotting power of the blood (anticoagulants) e.g. aspirin
- medicines to lower your blood pressure including betablockers, e.g. atenolol, bisoprolol.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine. However, as with all drugs Bupivacaine Infusion Solution should only be given in early pregnancy if absolutely necessary.

Driving and using machines:

Certain areas of your body will be numb for about 2-4 hours after having this medicine.

If this is likely to affect your ability to drive or use machinery you should wait for the effect to wear off. In general, it is wise to ask your doctor whether it is safe to drive.

Bupivacaine Infusion Solution contains sodium:

- Bupivacaine 0.1% w/w Solution for Infusion contains 347 mg sodium (main component of

- cooking/table salt) in each 100 ml.
- Bupivacaine 0.125% w/w Solution for Infusion contains 346 mg sodium (main component of cooking/table salt) in each 100 ml.

This quantity of sodium is equivalent to 17% of the recommend maximum daily dietary intake of sodium for an adult.

3. How Bupivacaine Infusion Solution is given to you

Bupivacaine Infusion Solution should only be administered by a doctor who will, in the case of an epidural infusion, have the necessary knowledge and experience in the technique of epidural anaesthesia.

Before administrating an epidural Infusion Solution, your doctor may inject a test dose of this medicine to ensure that the solution is not directed into a blood vessel.

Your doctor will decide on the most suitable dosage for you and may decide to reduce the dose if you are young, or elderly, or in a weak condition. If you are concerned about how much of this medicine you have received, speak to your doctor immediately.

If you have any further questions on the use of this product, 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 heartbeat
- problems passing water
- drooping of the upper eyelid, sunk in eye, flushing of the face (Horner's syndrome) are more commonly experienced in pregnant women.

Uncommon (may affect up to 1 in 100 people):

- feeling light-headed
- fits (seizures)

- ringing in the ears or being sensitive to sound
- difficulty in speaking
- numbness of the tongue or around the mouth
- blurred sight (vision)
- loss of consciousness
- shaking (tremors)
- twitching of your muscles.

Rare (may affect up to 1 in 1000 people):

- double vision
- nerve damage that may cause changes in sensation or muscle weakness (neuropathy). This may include peripheral nerve damage
- 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 legs
- weak or paralysed legs
- partial loss of movement (paresis)
- uneven heartbeat (arrhythmias). This could be life threatening
- slowed or stopped breathing or stopped heartbeat which 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 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: <https://yellowcard.mhra.gov.uk/> 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 Infusion Solution

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date printed on the infusion bag after EXP. The expiry date refers to the last day of the month. Do not store above 25°C.

Your doctor or the hospital will normally store this medicine and they are responsible for the quality of the product when it is opened if not used immediately. They are also responsible for correctly disposing of any unused solution.

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 infusion.

6. Contents of the pack and other information

The active substance is bupivacaine hydrochloride.

- **Bupivacaine Hydrochloride 0.1% w/v Solution for Infusion.** Each 1ml contains 1 mg of anhydrous bupivacaine hydrochloride equivalent to 1.055 mg of bupivacaine hydrochloride.
- **Bupivacaine Hydrochloride 0.125%w/v Solution for Infusion.** Each 1ml contains 1.25mg of anhydrous bupivacaine hydrochloride equivalent to 1.319 mg of bupivacaine hydrochloride.

The other ingredients are sodium chloride, sodium hydroxide and water for injection.

What Bupivacaine Infusion Solution looks like and contents of pack

Bupivacaine Infusion Solution is a colourless or almost colourless, aqueous, sterile solution for infusion and is available in two strengths. Both strengths are available in 100 ml or 250 ml plastic (polypropylene) bags for infusion in packs of 10 and 5 respectively.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Unicorn Pharmaceuticals Limited
Devonshire House
582 Honeypot Lane
Stanmore, HA7 1JS
United Kingdom

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