

Package leaflet: Information for the patient
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 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 or 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 symptoms 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, Bupivacaine Hydrochloride 0.5% w/v Solution for Injection. It will be referred to as Bupivacaine Hydrochloride Injection for ease hereafter.

In this leaflet:

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

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

Bupivacaine belongs to a group of medicines called amidetype anaesthetics.

Bupivacaine Hydrochloride 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.

Bupivacaine Hydrochloride Injection may be used as follows:

- as a local injection to produce numbness at the site of injection
- injected around a nerve to block the nerve and relieve pain
- injected around the spinal cord as an epidural to prevent or relieve pain, e.g. in labour, surgical operations including Caesarean section, and for post-operative pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN BUPIVACAINE HYDROCHLORIDE INJECTION

You should not be given Bupivacaine Hydrochloride Injection if :

- you know you are allergic to bupivacaine or to any other amide-type of local anaesthetic, or to any of the other ingredients (see Section 6 of this leaflet)
- you are to be injected in a vein of the hands or legs. (Bier's block).

Adrenaline containing bupivacaine should not be given for special techniques (like penile block, Oberst block) to numb the part of the body where areas with end arteries are affected.

You should not be given this Injection as an epidural if:

- you have an infection of the skin with pus at or near the site to be injected
- you 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
- you have problems with the clotting of your blood or are taking any anticoagulant drugs that thin the blood

- you are suffering from any infection, disease or tumour of the brain or spinal cord
- you have bleeding inside the head (intracranial haemorrhage)
- you have increased pressure within the brain.

Speak 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 **Bupivacaine Hydrochloride Injection**

- you suffer from any liver and kidney problems
- you suffer from any heart problem, particularly if it affects the heart rate
- you suffer from severe shock or low blood pressure
- you have breathlessness or restriction to breathing from fluid or a large tumour in the abdomen
- you have accumulation of fluid around the lungs
- you are elderly (senile) or in poor health
- you are in the late stages of pregnancy
- you suffer from blood poisoning (septicaemia)
- you have high blood pressure during pregnancy
- you have problems with the circulation of blood to the brain
- you have excess fluid in the womb during pregnancy (hydramnios)
- you have a tumour of the ovary or the womb
- you have accumulation of excess fat in your body
- you 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).

Other medicines and Bupivacaine Hydrochloride Injection :

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

Some drugs can interact with Bupivacaine Hydrochloride Injection which can significantly alter their effects.

These drugs include:

- lidocaine, amiodarone, mexiletine (or any other medicine with local anaesthetic effect) for controlling the heart's rhythm.

Some drugs may increase the risk of side effects with Bupivacaine Hydrochloride Injection in certain situations. These drugs include:

- an anticoagulant e.g. aspirin (to reduce the clotting power of the blood)
- medicines to lower your blood pressure including betablockers, e.g. atenolol, bisoprolol.

If you are already taking one of these medicines, speak to you doctor or nurse before you receive Bupivacaine Hydrochloride Injection.

Pregnancy, breastfeeding and fertility:

Tell your doctor/ nurse before you are given this medicine if you are pregnant, think you may be pregnant, are planning to become pregnant, or are breastfeeding. There is no evidence of harmful effects in pregnancy or breastfeeding. However as with all drugs, Bupivacaine Hydrochloride Injection should only be given in early pregnancy if absolutely necessary.

In children < 12 years as some injections of Bupivacaine Hydrochloride injection in order to numb parts of the body during surgery are not established in younger children. Bupivacaine Hydrochloride injection is not established in children < 1 year.

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.

Important information about Bupivacaine Hydrochloride Injection :

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

3. HOW TO TAKE BUPIVACAINE HYDROCHLORIDE INJECTION

Bupivacaine Hydrochloride Injection should only be administered by a doctor who will, in the case of an epidural injection, have the necessary knowledge and experience in the technique of epidural anaesthesia. Before administering an epidural Injection, your doctor may inject a test dose of Bupivacaine Hydrochloride Injection to ensure that the solution is not directed into a blood vessel.

Your doctor will decide on the most suitable dosage for your particular case 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.

Use in children and adolescents

Depending on the type of required analgesia Bupivacaine Hydrochloride 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 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 everyone 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.

Serious side effects

- Uneven heart beat or stopped heart beat. This could be life threatening

Other serious side effects are also rare, but may occur if too much Bupivacaine Hydrochloride Injection is given or if the drug is unintentionally injected into a blood vessel. If you notice any of the following effects inform your 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 1 to 10 people in 100)

- Being sick (Vomiting)
- Feeling dizzy
- Pins and needles
- High blood pressure
- Slow heart beat
- Problems in 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 (affects 1 to 10 people in 1000)

- Feeling light-headed
- Fits
- Ringing in the ears or being sensitive to sound
- Difficulty in speaking

- Numbness of the tongue
- Blurred sight
- Loss of consciousness
- Shaking
- Twitching of your muscles.

Rare (affects 1 to 10 people in 10,000)

- Double vision
- Nerve damage that may cause changes in sensation or muscle weakness. 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 legs
- Spinal cord injury (paraplegia)
- Partial loss of movement (paresis)
- Slowed or stopped breathing.

Possible side effects seen with other local anaesthetics which might also be caused by Bupivacaine Hydrochloride Injection 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
- Problems with the muscles of 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.

Do not be concerned by this list of possible side effects. You may not get any of them. If any of the side effect get serious or you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

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 HYDROCHLORIDE INJECTION

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

The solution should not be used after the expiry date printed on the ampoule and carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the container in the outer carton in order to protect from light.

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.

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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

The active substance is bupivacaine hydrochloride.

The other ingredients are sodium chloride and sodium hydroxide and water for Injection.

What Bupivacaine Hydrochloride Injection looks like and contents of pack

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

Bupivacaine Hydrochloride Injection 0.25%w/v. Each 1ml contains 2.5mg of anhydrous bupivacaine hydrochloride.

Bupivacaine Hydrochloride Injection 0.5%w/v. Each 1ml contains 5mg of anhydrous bupivacaine hydrochloride.

Both product strengths are available as either:

- 10ml and 20ml clear glass ampoules in packs of 10 or
- 10ml and 20ml individual sterile wrapped clear glass ampoules in packs of 10.

Marketing authorisation holder

Mercury Pharmaceuticals Limited,

Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

Manufacturer

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