



MercuryPharma

**PACKAGE LEAFLET: INFORMATION FOR THE PATIENT****Bupivacaine Hydrochloride 0.1% w/v Solution for Infusion  
Bupivacaine Hydrochloride 0.125% w/v Solution for Infusion****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 0.1% w/v Solution for Infusion, Bupivacaine Hydrochloride 0.125% w/v Solution for Infusion. It will be referred to as Bupivacaine Hydrochloride Infusion Solution for ease hereafter.

In this leaflet:

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

**1. WHAT BUPIVACAINE HYDROCHLORIDE INFUSION SOLUTION 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 anaesthetics.

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

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BUPIVACAINE HYDROCHLORIDE INFUSION SOLUTION****Do not take Bupivacaine Hydrochloride Infusion Solution 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).

**You should not be given this Infusion Solution 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 incomplete development of spine (Spina bifida)

- you have an abnormal connection between veins and arteries (AV malformation)
- 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 taking Bupivacaine Hydrochloride Infusion Solution

- you suffer from any liver, 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 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)
- you are elderly (senile) or in poor health
- 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 are in the late stages of pregnancy
- you suffer from blood poisoning (septicaemia).

**Other medicines and Bupivacaine Hydrochloride Infusion Solution:**

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 Infusion Solution which can significantly alter their effects. These drugs include:

- any medication used to regulate the heart beat such as lidocaine, amiodarone, mexiletine.  
Some drugs may increase the risk of side effects with Bupivacaine Hydrochloride Infusion Solution.  
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 your doctor or nurse before you receive Bupivacaine Hydrochloride Infusion Solution.**

**Pregnancy, breastfeeding and fertility:**

Tell your doctor/ nurse before you are given this medicine if you are pregnant, think you may be pregnant or are planning to become pregnant, or are breastfeeding. However, as with all drugs Bupivacaine Hydrochloride 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 Injection contains Sodium:**

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

**3. HOW TO TAKE BUPIVACAINE HYDROCHLORIDE INFUSION SOLUTION IS GIVEN TO YOU**

Bupivacaine Hydrochloride 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 administering an epidural Infusion Solution, your doctor may inject a test dose of Bupivacaine Hydrochloride Infusion Solution 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.

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.**

Other serious side effects are also rare, but may occur if too much Bupivacaine Hydrochloride Infusion Solution 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 less than 1 in 10 people):**

- Being sick (Vomiting)
- Feeling dizzy
- Pins and needles
- High blood pressure
- Slow heart beat
- 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 (affects less than 1 in 100 people)**

- 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 less than 1 in 1000 people):**

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

**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
- 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.

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](http://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 INFUSION SOLUTION

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

The solution should not be used after the expiry date printed on the infusion bag.

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 infusion.

If only part of an ampoule is used, the remaining solution should be discarded.

#### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

The active substance is bupivacaine hydrochloride.

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

**What Bupivacaine Hydrochloride Infusion Solution looks like and contents of pack**

Bupivacaine Hydrochloride Infusion Solution is a colourless or almost colourless, aqueous, sterile solution for infusion and is available in two strengths:

Bupivacaine Hydrochloride Infusion Solution 0.1%w/v. Each 1ml contains 1mg of anhydrous bupivacaine hydrochloride.

Bupivacaine Hydrochloride Infusion Solution 0.125%w/v. Each 1ml contains 1.25mg of anhydrous bupivacaine hydrochloride.

Both product strengths are available as 100ml or 250ml plastic (polypropylene) bags for infusion in packs of 10 and 5 respectively. Not all pack sizes may be marketed.

**Marketing authorization holder**

Mercury Pharma International Ltd,  
4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

**Company responsible for Manufacture:**

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