

## Package leaflet: Information for the user

### Bupivacaine 0.25% w/v, 0.5% w/v solution for injection 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 further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. 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 you use Bupivacaine solution for injection
3. How to use Bupivacaine solution for injection
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 hydrochloride is a local anaesthetic. It belongs to a group of medicines called amide- type local anaesthetics.

Bupivacaine solution for 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 during childbirth.
- Relieve pain in adults, infants and children above 1 year of age

You must talk to a doctor if you do not feel better or if you feel worse after {number of} days

#### **2. What you need to know before you use Bupivacaine solution for injection**

##### **Do not use Bupivacaine solution for injection:**

- 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
- adrenaline containing bupivacaine for special techniques (e.g. penile block, Oberst block) to numb parts of the body where areas with end arteries are affected.

You must not be given Bupivacaine solution for injection if any of the above apply to you. If you are not sure, talk to your doctor before you are given Bupivacaine solution for injection.

## Warnings and Precautions

Talk to your doctor before using Bupivacaine solution for injection.

- if you have heart, kidney or liver problems. This is because your doctor may need to adjust the dose of Bupivacaine solution for injection.
- 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.
- In children < 12 years as some injections of Bupivacaine solution for injection in order to numb parts of the body during surgery are not established in younger children. The use of Bupivacaine solution for injection is not established in children < 1 year of age.

If you are not sure if any of the above apply to you, talk to your doctor before you are given Bupivacaine solution for injection.

## Other medicines and Bupivacaine solution for injection

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This is because Bupivacaine solution for injection can affect the way some medicines work and some medicines can have an effect on Bupivacaine solution for injection.

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 solution for injection for you.

## Pregnancy and breast-feeding

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

## Driving and using machines

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

## Bupivacaine solution for injection contains Sodium

Each ml of Bupivacaine 0.25% w/v solution for injection contains 0.15 mmol (3.4 mg) of sodium. Each ml of Bupivacaine 0.5% w/v solution for injection contains 0.14 mmol (3.2 mg) of sodium. To be taken into consideration by patients on a controlled sodium diet.

## 3. How to use Bupivacaine solution for injection

Always take use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended 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 solution for injection 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 solution for injection. Your doctor will give you Bupivacaine solution for injection 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 solution for 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.

#### **If you have been given too much Bupivacaine solution for injection**

Serious side effects from getting too much Bupivacaine solution for 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 solution for 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 solution for injection 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 solution for injection, tell your doctor immediately.

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

#### **4. Possible side effects**

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

Severe allergic reactions (rare, affects less than 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 (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 (hypertension).
- Slow heartbeat.
- Problems passing water.

Uncommon (affects less than 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 (affects less than 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 heartbeat. This could be life-threatening.

Possible side effects seen with other local anaesthetics which might also be caused by Bupivacaine solution for 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 or problems with the muscles of the 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.

#### **Reporting of side effects**

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. You can also report side effects directly via

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

## **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 ampoule, vial and carton.

The expiry date refers to the last day of that month.

Do not refrigerate or freeze.

Bupivacaine Injection is for single use only and should be used immediately after opening. Discard any unused solution.

Do not use this medicine if you notice the contents are discoloured in any way or if particles are present.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Bupivacaine solution for injection contains**

The active substance is bupivacaine hydrochloride.

Bupivacaine 0.25% w/v solution for injection: Each 1 ml of solution contains 2.5 mg of anhydrous Bupivacaine hydrochloride.

Bupivacaine 0.5% w/v solution for injection: Each 1 ml of solution contains 5 mg of anhydrous Bupivacaine hydrochloride.

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

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

Bupivacaine solution for injection is a clear, colourless, sterile solution for injection. It is available in two strengths, 0.25% w/v and 0.5% w/v. Both product strengths are available in ampoule and vial.

Bupivacaine 0.25% w/v solution for injection is filled in 5 ml and 10 ml ampoules and also in 20 ml vials.

Bupivacaine 0.5% w/v solution for injection is filled in 2 ml, 4 ml, 5 ml and 10 ml ampoules and also in 20 ml vials.

The 2 ml, 4 ml and 5 ml ampoules are supplied in packs of 5 and 10 ampoules. The 10 ml ampoules are supplied in packs of 5, 10, 15 and 20 ampoules. The 20 ml vials are supplied in packs of 1 vial.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Accord Healthcare Limited, Sage House, 319 Pinner Road, North Harrow, Middlesex HA1 4HF, United Kingdom

For any further information about this medicinal product, please contact the Marketing Authorisation Holder

**This leaflet was last revised in 04/2014**