## 1.3 Product information

### 1.3.1 SPC, labelling and package leaflet

#### 1.3.1.1 Package leaflet

Enclosed in subsequent pages,

**Package leaflet: Information for the user**

**<Invented Name> 2.5 mg/ml solution for injection**
**<Invented Name> 5 mg/ml solution for injection**
**Bupivacaine Hydrochloride Anhydrous**

**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 <Invented name> is and what it is used for

<Invented name> contains the active substance bupivacaine hydrochloride. It belongs to a group of medicines called amide-type local anaesthetics.

<Invented name> 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

## 2. What you need to know before <Invented name> is given to you

**You must not be given <Invented name>:**
- 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 (coagulation disorder) or ongoing anticoagulation treatment.
- 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
- If you are having obstetrical paracervical block (a type of anaesthesia given during labour).

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

**Warnings and Precautions**
Talk to your doctor or nurse before having <Invented name>.
- if you have heart , kidney or liver problems. This is because your doctor may need to adjust the dose of <Invented name>.
- 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.
- if you have epilepsy.
- 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.

**Children**
- In children aged less than 12 years: As some injections of <Invented name> in order to numb parts of the body during surgery are not established in younger children. The use of <Invented name> 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 <Invented name>.

**Other medicines and <Invented name>**
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 <Invented name> can affect the way some medicines work and some medicines can have an effect on <Invented name>.

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 <Invented name> for you.

**Pregnancy , breast-feeding and fertility**
Pregnancy
There are no or limited amount of data from the use of Bupivacaine in pregnant women. 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 this medicine is administered to you.

Breastfeeding
Bupivacaine enters the mother's milk, if you are breast-feeding you should discuss options with your doctor.

Fertility
There are no data on the effect of bupivacaine hydrochloride on human fertility.

**Driving and using machines**
<Invented name> may make you feel sleepy and affect the speed of your reactions. After you have been given <Invented name>, you should not drive or use tools or machines until the next day.

**<Invented name> 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 <Invented name>

<Invented name> 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.

<Invented name> will be given to you as an injection or infusion. The part of the body where you are injected will depend on why you are being given <Invented name>. Your doctor will give you <Invented name> 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 <Invented name> 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 <Invented name>**
Serious side effects from getting too much <Invented name> 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 <Invented name> 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 <Invented name> as soon as these signs appear. This means that if any of these happen to you, or you think you have received too much <Invented name>, tell your doctor immediately.

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

If you have any further questions on the use of the 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 heartbeat.
- 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 heartbeat. This could be life-threatening.

**Possible side effects seen with other local anaesthetics which might also be caused by <Invented name> 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V.

## 5. How to store <Invented name>

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 use this medicine if you notice the contents are discoloured in any way or if particles are present.
Do not refrigerate or freeze.
Your doctor or the hospital will normally store <Invented name> 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 <Invented name> correctly.

## 6. Contents of the pack and other information

**What Bupivacaine solution for injection contains**
The active substance is bupivacaine hydrochloride.
Bupivacaine 2.5 mg/ml solution for injection:
Each ml contains 2.5 mg bupivacaine hydrochloride (as monohydrate)
Each 5 ml contains 12.5 mg bupivacaine hydrochloride (as monohydrate)
Each 10 ml contains 25 mg bupivacaine hydrochloride (as monohydrate)
Each 20 ml contains 50 mg bupivacaine hydrochloride (as monohydrate)

Bupivacaine 5 mg/ml solution for injection:
Each ml contains 5 mg bupivacaine hydrochloride (as monohydrate)
Each 2 ml contains 10 mg bupivacaine hydrochloride (as monohydrate)
Each 4 ml contains 20 mg bupivacaine hydrochloride (as monohydrate)
Each 5 ml contains 25 mg bupivacaine hydrochloride (as monohydrate)
Each 10 ml contains 50 mg bupivacaine hydrochloride (as monohydrate)
Each 20 ml contains 100 mg bupivacaine hydrochloride (as monohydrate)

The other ingredients are water for injections, sodium chloride and sodium hydroxide (E524) (for pH adjustment).

**What <Invented name> looks like and contents of the pack**
Bupivacaine solution for injection is a clear, colourless, sterile solution for injection. It is available in Type I clear glass ampoules and Type I clear glass vials with rubber stopper and flip-off seal.

Bupivacaine 2.5 mg/ml solution for injection:
5 ml white band ampoules are supplied in packs of 5 and 10 ampoules
10 ml green band ampoules are supplied in packs of 5, 10, 15 and 20 ampoules
20 ml vials with chlorobutyl rubber stopper and orange flip-off seal are supplied in pack of 1 vial.

Bupivacaine 5 mg/ml solution for injection:
2 ml two orange ring ampoules are supplied in packs of 5 and 10 ampoules
4 ml red band ampoules are supplied in packs of 5 and 10 ampoules
5 ml blue band ampoules are supplied in packs of 5 and 10 ampoules
10 ml yellow band ampoules are supplied in packs of 5, 10, 15 and 20 ampoules
20 ml vials with chlorobutyl rubber stopper and red flip-off seal are supplied in pack of 1 vial

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
< To be completed nationally>

**Manufacturer**
< To be completed nationally>

**This medicinal product is authorised in the Member States of the EEA under the following names:**
< To be completed nationally>

**This leaflet was last revised in {MM/YYYY}.**
< To be completed nationally>

**The following information is intended for healthcare professionals only**

**Bupivacaine 2.5 mg/ml solution for injection**
**Bupivacaine 5 mg/ml solution for injection**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**Administration**

Solution for injection.
The medicinal product is for percutaneous infiltration, intra-articular block, peripheral nerve block(s) and central neural block (caudal or epidural) use only.

The clinician's experience and knowledge of the patient's physical status is important in calculating the required dose. The lowest dose required for adequate anaesthesia should be used. An overall dose limit of 150 mg should not be exceeded. A dose of 400 mg administered over 24 hours is well tolerated in the average adult, which does not include the initial bolus dose, can be used routinely. For the paediatric patient's lowest dose required for adequate analgesia should be used.

**Handling Instructions**

For single use only.
Only clear solutions practically free from particles should be used. Any unused solution should be discarded.
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.

Method for preparation of 1.25 mg/ml concentration:
Bupivacaine 2.5 mg/ml solution for injection:

- Withdraw 250 ml of diluent from 500 ml non-pvc diluent bag/bottle and inject 250 ml of Bupivacaine 2.5 mg/ml solution for injection into 500 ml non pvc diluent bag/bottle to get final concentration 1.25 mg/ml.
- The diluent bag/bottle should be gently shaken for the drug uniformity.

Bupivacaine 5 mg/ml solution for injection:

- Withdraw 125 ml of diluent from 500 ml non-pvc diluent bag/bottle and inject 125 ml of Bupivacaine 5 mg/ml solution for injection into 500 ml non pvc diluent bag/bottle to get final concentration 1.25 mg/ml.
- The diluent bag/bottle should be gently shaken for the drug uniformity.

Method for preparation of 2.5 mg/ml concentration:
Bupivacaine 5 mg/ml solution for injection:

- Withdraw 250 ml of diluent from 500 ml non-pvc diluent bag/bottle and inject 250 ml of Bupivacaine 5 mg/ml solution for injection into 500 ml non pvc diluent bag/bottle to get final concentration 2.5 mg/ml.
- The diluent bag/bottle should be gently shaken for the drug uniformity.

Bupivacaine is compatible when admixed with 0.9% w/v (9 mg/ml) sodium chloride injection and Ringer Lactate Solution. However, this medicinal product must not be mixed with other medicinal products.

**Storage information**

Do not refrigerate or freeze.

After first opening: to be used immediately.

Shelf life after dilution:
Chemical and physical in-use stability has been demonstrated for 7 days at 20°C - 25°C in Non-PVC containers. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2 to 8°C, unless reconstitution / dilution (etc.) has taken place in controlled and validated aseptic conditions.