Package leaflet: Information for the user

Bupivacaine 2.5 mg/ml solution for injection
Bupivacaine 5 mg/ml solution for injection
Bupivacaine Hydrochloride Anhydrous

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

Bupivacaine solution for injection contains the active substance bupivacaine hydrochloride. 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

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
- If you are having obstetrical paracervical block (a type of anaesthesia given during labour).

- 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.

Children
- In children aged less than 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 less than 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 includes medicines that you buy without a prescription and herbal 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.

Bupivacaine may get into breast milk. If you are breast-feeding you should discuss options with your doctor.

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

Bupivacaine solution for injection will be given to you by a doctor. Your doctor will know the correct way to give you this medicine.

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 take more Bupivacaine solution for injection than you should
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.

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 everyone 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 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
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie

e-mail: medsafety@hpra.ie.

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 use this medicine if you notice the contents are discoloured in any way or if particles are present.
Do not refrigerate or freeze.
Bupivacaine solution for injection is for single use only and should be used immediately after opening. Discard any unused solution.
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 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 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 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
Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer

Accord Healthcare B.V.,
Winthontlaan 200,
3526 KV Utrecht,
The Netherlands

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	**Name of the medicinal product**
Austria	Bupivacain Accord 2.5mg/ml, 5mg/ml injektionslösung
Belgium	Bupivacaine Accord Healthcare 2,5mg/ml, 5mg/ml oplossing voor injectie / solution injectable/ injektionslösung
Bulgaria	Bupivacaine Accord 2.5mg/ml, 5mg/ml solution for injection
Cyprus	Bupivacaine Accord 5mg/ml solution for injection
Czech Republic	Bupivacaine Accord 2,5 mg/ml, 5 mg/ml Injekční roztok
Germany	Bupivacainhydrochlorid Accord 2,5 mg/ml,5 mg/ml Injektionslösung
Denmark	Bupivacain Accord 2.5mg/ml, 5mg/ml injektionsvæske, opløsning
Estonia	Bupivacaine Accord 5mg/ml süstelahus
Spain	Bupivacaina Accord 2.5mg/ml, 5mg/ml solución inyectable
Finland	Bupivac/aine Accord 2.5mg/ml, 5mg/ml injektioneste, liuos
France	Bupivacaine Accord 2.5mg/ml, 5mg/ml solution injectable
Italy	Bupivacaina Accord
Lithuania	Bupivacaine Accord 2.5mg/ml, 5mg/ml injekcinis tirpalas
Latvia	Bupivacaine Accord 5mg/ml šķīdums injekcijām
Malta	Bupivacaine Accord 2.5mg/ml, 5mg/ml solution for injection
Netherland	Bupivacaine Accord 2.5mg/ml, 5mg/ml oplossing voor injectie
Norway	Bupivacaine Accord
Poland	Bupivacaine Accord 5mg/ml
Sweden	Bupivacaine Accord
Slovenia	Bupivakain Accord 2,5mg/ml, 5mg/ml raztopina za injiciranje
Slovak Republic	Bupivacaine Accord 2.5mg/ml, 5mg/ml Injekčný roztok
Ireland	Bupivacaine 2.5mg/ml, 5mg/ml solution for injection
Portugal	Bupivacaine Accord 2.5mg/ml, 5mg/ml Solução injetável

This leaflet was last revised in 05/2022.

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.