Package leaflet: Information for the user

Levobupivacaine 2.5 mg/ml solution for injection/infusion

Levobupivacaine

Read all of this leaflet carefully before you start taking 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, nurse or pharmacist.
- If you get any side effects talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Levobupivacaine 2.5 mg/ml is and what it is used for

Levobupivacaine 2.5 mg/ml belongs to a group of medicines called local anaesthetics. This type of medicine is used to make an area of the body numb or free from pain.

Adults:
Levobupivacaine 2.5 mg/ml is used as a local anaesthetic to make numb parts of the body before a major surgery (for example, as an epidural for caesarean section) and minor surgeries (such as on eye and mouth.)

It is also used for pain relief:
- After Major Surgery
- During childbirth

Children:
Levobupivacaine 2.5 mg/ml may also be used in children to numb parts of the body before a surgery and for pain relief after a minor surgery, such as the repair of a groin hernia.

Levobupivacaine 2.5 mg/ml has not been tested in children less than 6 months of age.

2. What you need to know before you use Levobupivacaine 2.5 mg/ml

Do not use Levobupivacaine 2.5 mg/ml:

- If you are allergic (hypersensitive) to levobupivacaine, to any similar local anaesthetics or to any of the other ingredients of this medicine (listed in section 6).
- If you have very low blood pressure.
- As a type of pain relief given by injection into the area around the neck of the womb (the cervix) during the early stage of labour (paracervical block).
- To numb an area of the body by injecting Levobupivacaine 2.5 mg/ml into a vein.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Levobupivacaine 2.5 mg/ml if you have any of the following diseases or conditions below. You may need to be checked more closely or be given a smaller dose.

- If you suffer from a heart condition

- If you suffer from a disease of the nervous system
- If you are weak or ill
- If you are elderly
- If you have liver disease.

Other medicines and Levobupivacaine 2.5 mg/ml:

Tell your doctor, pharmacist or nurse if you are taking, using or have recently taken or might take any other medicines even those that may be acquired without a medical prescription. Particularly, if you are taking medicines for:

- Irregular heartbeats (such as mexiletine)
- Fungal infections (such as ketoconazole) since this may affect how long Levobupivacaine 2.5 mg/ml stays in your body
- Asthma (such as theophylline) since this may affect how long Levobupivacaine 2.5 mg/ml stays in your body.

Pregnancy, breast-feeding and fertility

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

Levobupivacaine 2.5 mg/ml must not be a given for pain relief by injection into the area around the neck of the womb or cervix during childbirth (known as paracervical block).

The effect of Levobupivacaine 2.5 mg/ml on the child during the early stage of pregnancy is not known. Therefore, Levobupivacaine 2.5 mg/ml should not be used during the first three months of your pregnancy, unless your doctor thinks it is necessary.

It is not known if levobupivacaine passes into breast milk. However, from the experience with similar drugs, only small amounts of levobupivacaine are expected to pass into breast milk. Breast-feeding is therefore possible after having a local anaesthetic.

Driving and using machines

The use of Levobupivacaine 2.5 mg/ml can have a considerable effect on the ability to drive or use machiness. You must not drive or operate machinery until the effects of Levobupivacaine 2.5 mg/ml and the inmediate effects of surgery have worn off. Make sure you get advice about this matter from the doctor or nurse who is treating you, before leaving hospital.

Important information about some of the ingredients of Levobupivacaine 2.5 mg/ml:

This medicinal product contains 3.5 mg/ml sodium in the bag or ampoule solution which shall be taken into consideration with patients on a controlled sodium diet.

3. How to use Levobupivacaine 2.5 mg/ml

Your doctor will give you Levobupivacaine 2.5 mg/ml by injection through a needle or into a small tube in your back (epidural). Levobupivacaine 2.5 mg/ml can also be injected into other parts of the body to numb the area that you will have treated, such as the eye, arm or leg.

Your doctor and nurse will watch you carefully while you are being given Levobupivacaine 2.5 mg/ml

Dosage

The amount of Levobupivacaine 2.5 mg/ml you will be given and how often it is given will depend on why it is being used and also on your health, age and weight. The smallest dose that can produce numbness in the required area will be used. The dose will be carefully worked out by your doctor.

When Levobupivacaine 2.5 mg/ml is used for pain relief during labour or for childbirth by caesarean section (an epidural), the dose used should be particularly carefully controlled.

If you get more Levobupivacaine 2.5 mg/ml than you should

If you get more Levobupivacaine 2.5 mg/ml than you should, you may have numbness of the tongue, dizziness, blurred vision, muscle twitching, severe breathing difficulties (including stopping breathing) and even fits (convulsions). If you notice any of these symptoms, tell your doctor immediately. Sometimes too much Levobupivacaine 2.5 mg/ml may also cause low blood pressure, bradycardia or tachicardia and changes in your heart rhythm. Your doctor may need to give you other medicines to help stop these symptoms. If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you consider you are having some of the side effects listed below, report immediately to you doctor or nurse. Some side effects with Levobupivacaine 2.5 mg/ml can be serious.

Very common side effects (may affect more than 1 in 10 people):
- Feeling tired or weak, short of breath, looking pale (these are all signs of anaemia)
- Low blood pressure
- Nausea

Common side effects (may affect up to 1 in 10 people)
- Dizziness
- Headache
- Vomiting
- Problems (distress) for an unborn child
- Back pain
- Fever
- Pain after surgery

Not known (frequency cannot be estimated from the available data):
- Serious allergic (hypersensitive) reactions causing severe breathing and swallowing difficulties, hives and very low blood pressure.
- Allergic (hypersensitive) reactions recognized by red itchy skin, sneezing, sweating a lot, rapid heartbeat, fainting or swelling of the face, lips and mouth.
- Convulsions
- Drowsiness
- Blurred vision
- Breathing stopping
- Heart block or heart stopping
- Localized tingling
- Numbness of the tongue
- Muscle weakness or twitching
- Loss of bladder or bowel control
- Paralysis
- Tingling, numbness or other abnormal sensation
- Prolonged erection of the penis that may be painful
- Nerve disorder which can include drooping of the eyelid, small pupil (black center of the eye), sunken eye socket, sweating and/or redness in one side of the face

Bradycardia, tachycardia, or irregular heartbeats, and heart rhythm changes that can be seen on an ECG, have also been reported as side effects.

Rarely, some side effects may be long-term or permanent.

If you consider that some of the side effects you experience become worse or if you notice any side effect not mentioned in this leaflet, report it to 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 national reporting system Yellow Card Scheme Website: 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 Levobupivacaine 2.5 mg/ml

This medicinal product does not require special preservation

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

Do not use Levobupivacaine 2.5 mg/ml after the expiry date shown on the label 'Exp.' The expiry date refers to the last day of the stipulated month.

Your doctor will store this medicine for you.

The solution should be used immediately after opening.

Levobupivacaine 2.5 mg/ml should not be used if there are visible particles in it.

Medicines should not be disposed of through wastewater or household waste. These measures will help to protect the environment.

6. Contents of the pack and other information

What Levobupivacaine 2.5 mg/ml contains

The active substance is levobupivacaine (as hydrochloride).

A milliliter of solution contains 2.5 mg of levobupivacaine (as hydrochloride). Each 10 ml ampoule contains 25 mg.

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

What the product looks like and contents of the pack

Levobupivacaine 2.5 mg/ml is a clear, colourless solution which comes in type-1 glass ampoules.

Each ampoule contains 25 mg of levobupivacaine in one 10 ml ampoule. It is supplied in packages of 5 and 10 ampoules.

Not all pack sizes may be marketed

Marketing Authorisation Holder and manufacturing responsible:
Marketing Authorisation Holder:
Altan Pharmaceuticals, S.A.
C/ Cólquide Nº 6, Portal 2, 1ª Planta, Oficina F. Edificio Prisma
Las Rozas, 28230 Madrid, Spain

Manufacturing Responsible:
Altan Pharmaceuticals, S.A.
Avda Constitución 198-199
Pol. Ind. Monte Boyal
45950 Casarrubios del Monte, Toledo.
Spain

OTHER PRESENTATIONS
Levobupivacaine 5.0 mg/ml solution for injection/infusion
Levobupivacaine 7.5 mg/ml solution for injection/infusion

Levobupivacaine 1.25 mg/ml solution for infusion
Levobupivacaine 0.625 mg/ml solution for infusion

This leaflet was last revised in 05/2025

The following information is intended for medical or health professionals only:

Instructions for use and handling
Levobupivacaine 2.5 mg/ml is intended for single. Discard any unused solution.

From a microbiological point of view, the product should be used immediately after opened. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user. Experience on the security of the treatment with levobupivacaine for more than 24 hrs is limited.

Expiration after the first opening: the product should be used immediately.

Expiration after dilution with a solution of 0.9% sodium chloride: Chemical and physical stability in use have been demonstrated in 0,9% sodium chloride solutions for 7 days at 20-22°C.

As for all parenteral medicinal products, the solution/dilution should be inspected visually prior to use. Only clear solutions without visible particles should be used.

Standard dilutions of levobupivacaine should be done with 9 mg/ml (0.9%) sodium chloride solution for injection and implementing aseptic techniques.

It has been demonstrated that 8.4 micrograms/ml of clonidine, 0.05 mg/ml of morphine and 4 micrograms/mL of fentanyl are compatible with levobupivacaine in a 9 mg/ml sodium chloride solution for injection (0.9%). Chemical and physical stability in use have been demonstrated with clonidine, morphine or fentanyl for 40 hours at 20-22°C.

Levobupivacaine 2.5 mg/ml should not be mixed with other medicinal products except those listed above. Dissolution with alkaline solutions such as sodium bicarbonate can produce precipitation.

Method of administration

Levobupivacaine should be administered only by, or under the supervision of, a clinician having the necessary training and experience.

Please refer to the summary of product characteristics for posology information.

Careful aspiration before and during injection is recommended to prevent intravascular injection.

Aspiration should be repeated before and during the administration a bolus doses, that should be injected slowly and increasing dosage at a speed of 7.5 - 30 mg/min, monitoring vital functions of the patient and keeping verbal contact with the same.

If toxic symptoms occur, the injection should be stopped immediately.