Package leaflet: Information for the user

Levobupivacaine 1.25 mg/ml solution for infusion
Levobupivacaine

Read all of this leaflet carefully before you start taking this medicine, because it has 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Levobupivacaine 1.25 mg/ml is and what it is used for

Levobupivacaine 1.25 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.

Levobupivacaine 1.25 mg/ml solution for infusion is for adult use only. Levobupivacaine 1.25 mg/ml is used for pain relief:
- after major surgery
- during childbirth

2. What you need to know before you are given Levobupivacaine 1.25 mg/ml

Do not use Levobupivacaine 1.25 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 by injecting Levobupivacaine 1.25 mg/ml into a vein.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Levobupivacaine 1.25 mg/ml if you have any of the following diseases or conditions. You may need to be checked more closely or be given a smaller dose.
- If you suffer from diseases of the nervous system
- If you are weak or ill
- If you are elderly
- If you have liver disease.

Other medicines and Levobupivacaine 1.25 mg/ml:

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

- Irregular heartbeats (such as mexiletine)

- Fungal infections (such as ketoconazole) since this may affect how long Levobupivacaine 1.25 mg/ml stays in your body
- Asthma (such as theophylline) since this may affect how long Levobupivacaine 1.25 mg/ml stays in your body.

Pregnancy, breast-feeding and fertility

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

Levobupivacaine 1.25 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 (paracervical block).

The effect of Levobupivacaine 1.25 mg/ml in child during the early stage of pregnancy is not known.

Therefore, Levobupivacaine 1.25 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 a similar drug, 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 can have a considerable effect on the ability to drive or use machines. You must not drive or operate machinery until all the effects of Levobupivacaine and the immediate 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 ingredients of Levobupivacaine 1.25 mg/ml:
This medicinal product contains 15 mmol (3.5 mg/ml) sodium per 100 ml bag and 30 mmol (3.5 mg/ml) sodium per 200 ml bag which shall be taken into consideration by patients on a controlled sodium diet.

3. How to use Levobupivacaine 1.25 mg/ml

Your doctor will give you Levobupivacaine 1.25 mg/ml by injection through a needle or small tube in your back (epidural). Your doctor and nurse will watch you carefully while you are being given Levobupivacaine 1.25 mg/ml.

Dosage

Adults:

The amount of Levobupivacaine 1.25 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 1.25 mg/ml is used for pain relief during childbirth, the dose used should be carefully controlled.

Children:
Not recommended.

If you get more Levobupivacaine 1.25 mg/ml than you should

If you get more Levobupivacaine 1.25 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 convulsions. If you notice any of these symptoms, tell your doctor immediately. Sometimes too much Levobupivacaine 1.25 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.

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 1.25 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

Other side effects (Unknown 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
- Fainting
- Drowsiness
- Blurred vision
- Stop of breath
- Heart attack or blockage
- Localized tingling
- Numbness of the tongue
- Muscle weakness or twitching
- Loss of bladder or bowel control
- Paralysis
- Seizures
- 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 or 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 1.25 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 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 1.25 mg/ml should not be used if there are visible particles in it.

Medicines should not be disposed of through wastewater or household waste. Ask the pharmacist for instructions to dispose packages and medicinal products you do not need anymore. These measures will help to protect the environment.

6. Contents of the pack and other information

What Levobupivacaine 1.25 mg/ml solution for infusion contains

The active substance is levobupivacaine (as hydrochloride).

Levobupivacaine 1.25 mg/ml: 1 ml contains 1.25 mg levobupivacaine (as hydrochloride).

The other ingredients are water for injections, sodium chloride, sodium hydroxide and a small quantity of hydrochloric acid.

What the product looks like and contents of the pack

Levobupivacaine 1.25 mg/ml is a clear, colourless solution. Each Polypropylene or PVC-free polyolefin bags contains 100 ml or 200 ml solution. It is supplied in packs of 5 and 24 bags of 100ml solution and 12 bags of 200 ml solution.

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.
P.I. Bernedo S/N.
01118 Bernedo, Álava.
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The following information is intended for medical or health professionals only:

Instructions for use and handling

Levobupivacaine 1.25 mg/ml is intended for single, epidural use only and must not be used for intravenous administration. Do not use unless the solution is clear and container is undamaged. Discard any unused solution.

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.

There is limited safety experience with levobupivacaine therapy for periods exceeding 24

hours. Shelf life after dilution in sodium chloride solution 0.9%:
Chemical and physical in-use stability has been demonstrated for both levobupivacaine 0.625 mg/ml and 1.25 mg/ml with 8.3-8.4 micrograms/ml clonidine, 50 micrograms /ml morphine and 2 micrograms /ml fentanyl, stored for 30 days at either 2-8°C or 20-22°C. Chemical and physical in-use stability has been demonstrated for both levobupivacaine 0.625 mg/ml and 1.25 mg/ml with sufentanyl added in a concentration of 0.4 micrograms /ml and stored for 30 days at 2-8°C or 7 days at 20-22°C.

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 would normally not be longer than 24 hours at 2-8°C, unless the mix has been prepared in controlled and validated aseptic conditions.

Levobupivacaine 1.25 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 infusion is recommended to prevent intravascular injection. If toxic symptoms occur, the injection should be stopped immediately.