Package leaflet: Information for the user

Levobupivacaine 7.5 mg/ml solution for injection/ infusion

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, please 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

Your medicine is called 'Levobupivacaine solution for injection/infusion' but is referred to as 'Levobupivacaine' throughout this leaflet.

1. What Levobupivacaine is and what it is used for

Levobupivacaine 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 is used **in adults to numb parts of the body**
- before major surgery (except for caesarean section)
- before minor surgery (such as on the eye and mouth).

Levobupivacaine is also used **in adults** for **pain relief**:
- after major surgery

Levobupivacaine can also be used **in children**
- to numb parts of the body before surgery
- for pain relief after minor surgery, such as the repair of a groin hernia.

Levobupivacaine has not been tested in children less than 6 months of age.

2. What you need to know before you are given Levobupivacaine

You should not be given Levobupivacaine:
- if you are **allergic** 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**
- to numb an area by injecting Levobupivacaine **into a vein**
- as pain relief **during labour**

Warnings and precautions
Talk to your doctor or nurse before you are given Levobupivacaine if you have any of the diseases or conditions below. You may need to be checked more closely or given a smaller dose.

- if you have a **heart condition**
- 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
Tell your doctor or nurse if you are taking or have recently taken or might take any other medicines, particularly medicines for:

- **irregular heartbeats** (such as mexiletine)
- **fungal infections** (such as ketoconazole) since this may affect how long Levobupivacaine stays in your body
- **asthma** (such as theophylline) since this may affect how long Levobupivacaine stays in your body.

Pregnancy, breast-feeding and fertility
Levobupivacaine should **not** be used during the **first three months** of your pregnancy, unless your doctor thinks it is necessary. This is because the effect of Levobupivacaine on the unborn child during the early stages of pregnancy is not known.

You may breast-feed after being given this medicine as only small amounts of levobupivacaine are expected to pass into breast milk.
If you are pregnant, breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before you are given this medicine.

Driving and using machines
You must not drive or operate machinery until all the effects of Levobupivacaine have worn off, as well as the effects of surgery. Talk to your doctor or nurse about this before leaving hospital.

Important information about some of the ingredients of Levobupivacaine
This medicine contains 36 mg sodium per ampoule, equivalent to 1.8% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

3. How you will be given Levobupivacaine

Levobupivacaine can be injected into 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.

Dosage
The amount of Levobupivacaine 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.

If you are given more Levobupivacaine 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 may also cause low blood pressure, fast or slow heartbeats 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.

Tell your doctor or nurse immediately if you notice any of the following **serious side effects.**
- feeling tired or weak, short of breath, looking pale (these are all signs of anaemia)
- serious allergic reactions which cause severe breathing difficulties, difficulty in swallowing, hives, very low blood pressure and swelling of the tongue or throat.
- paralysis
- fits (convulsions)

Other side effects that may also occur:

Very common (may affect more than 1 in 10 people)
- low blood pressure
- nausea

Common (may affect up to 1 in 10 people)
- dizziness
- headache
- vomiting
- back pain
- high body temperature (fever)
- pain after surgery

Not known (frequency cannot be estimated from the available data)
- allergic reactions recognised by red itchy skin, sneezing, sweating a lot, rapid heartbeat, fainting or swelling of the face, lips and mouth
- drowsiness
- blurred vision
- localized tingling
- numbness of the tongue
- muscle weakness or twitching
- loss of bladder or bowel control

- 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 centre of the eye), sunken eye socket, sweating and/or redness in one side of the face
- breathing stopping
- heart block or heart stopping
- loss of consciousness

Fast, slow 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.

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 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

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 label. The expiry date refers to the last day of that month.
Your doctor will store this medicine for you.
The solution should be used immediately after opening
The solution 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 contains
The active substance is levobupivacaine (as hydrochloride).
Each 1 ml contains 7.5 mg levobupivacaine (as hydrochloride).
Each 10 ml ampoule contains 75 mg levobupivacaine.
The other ingredients are water for injection, sodium chloride, sodium hydroxide and hydrochloric acid.

What Levobupivacaine looks like and contents of the pack
Levobupivacaine is a clear solution in colourless glass ampoules.
It is supplied in packs of 5 or 10 ampoules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Istituto Biochimico Italiano G. Lorenzini SpA,
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Manufacturer
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The following information is intended for medical or health professionals only:

Instructions for use and handling
Levobupivacaine 7.5mg/ml solution for injection/infusion is intended for single use only. Discard any unused solution.
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.
There is limited safety experience with levobupivacaine therapy for periods exceeding 24 hours.
Shelf life after first opening: The product should be used immediately.
Shelf life after dilution in sodium chloride solution 0.9%: Chemical and physical in-use stability has been demonstrated 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.

Dilutions of levobupivacaine standard solutions should be made with sodium chloride 9 mg/ml (0.9%) solution for injection using aseptic techniques.

Clonidine 8.4 µg/ml, morphine 0.05 mg/ml and fentanyl 4 µg/ml have been shown to be compatible with levobupivacaine in sodium chloride 9 mg/ml (0.9%) solution for injection. Chemical and physical in-use stability with clonidine, morphine or fentanyl has been demonstrated for 40 hours at 20-22°C.

Levobupivacaine must not be mixed with any other medicinal products except those listed above. Dilution with alkaline solutions such as sodium bicarbonate may result in precipitation.

Method of administration
Levobupivacaine should only be administered by/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 administration of a bolus dose, which should be injected slowly and in incremental doses, at a rate of 7.5–30 mg/min, while closely observing the patient's vital functions and maintaining verbal contact.
If toxic symptoms occur, the injection should be stopped immediately