

Package leaflet: Information for the user

Chirocaine 1.25 mg/ml solution for infusion For epidural use only

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, 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

1. What Chirocaine is and what it is used for
2. What you need to know before you are given Chirocaine
3. How you will be given Chirocaine
4. Possible side effects
5. How to store Chirocaine
6. Contents of the pack and other information

1. What Chirocaine is and what it is used for

Chirocaine 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.

Chirocaine solution for infusion is for adult use only.

Chirocaine is used for pain relief:

- after major surgery
- during childbirth

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

Do not take Chirocaine:

- 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 Chirocaine into a vein

Warnings and precautions

Talk to your doctor or nurse before you are given Chirocaine 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 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 Chirocaine

Tell your doctor or nurse if you are taking or have recently taken or might take any other medicines. In particular, tell them if you are taking medicines for:

- irregular heart beats (such as mexiletine)
- fungal infections (such as ketoconazole) since this may affect how long Chirocaine stays in your body
- asthma (such as theophylline) since this may affect how long Chirocaine stays in your body.

Pregnancy, breast-feeding and fertility

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 taking this medicine.

Chirocaine must not be given for pain relief by injection into the area around the neck of the womb or cervix during childbirth (paracervical block).

The effect of Chirocaine on the child during the early stage of pregnancy is not known. Therefore, Chirocaine 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 Chirocaine 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 Chirocaine 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 of the ingredients of Chirocaine

This medicinal product contains 3.5 mg/mL sodium in the bag or ampoule solution to be taken into consideration by patients on a controlled sodium diet.

3. How you will be given Chirocaine

Your doctor will give you Chirocaine through a small tube in your back (epidural). Your doctor and nurse will watch you carefully while you are being given Chirocaine.

Dosage

Adults:

The amount of Chirocaine 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 Chirocaine is used for pain relief during childbirth the dose used should be particularly carefully controlled.

Children:

Not recommended.

If you get more Chirocaine than you should

If you get more Chirocaine 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 Chirocaine 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. Some side effects with Chirocaine can be serious.

Tell your doctor or nurse immediately if you notice any of the following side effects.

Very common: may affect more than 1 in 10 people

- feeling tired or weak, short of breath, looking pale (these are all signs of anaemia)

Common: may affect up to 1 in 10 people

- problems (distress) for an unborn child

Not known: frequency cannot be estimated from the available data

- serious allergic (hypersensitive) reactions which cause severe breathing difficulties, difficulty in swallowing, hives, very low blood pressure and swelling of the tongue or throat.
- breathing stopping
- heart block or heart stopping
- loss of consciousness
- 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 (hypersensitive) 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 center of the eye), sunken eye socket, sweating and/or redness in one side of the face

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 or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

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 Chirocaine

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date shown 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 Chirocaine contains

The active substance is levobupivacaine (as hydrochloride).

Chirocaine 1.25 mg/ml solution for infusion: One ml contains 1.25 mg levobupivacaine (as the hydrochloride).

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

What Chirocaine looks like and contents of the pack

Chirocaine is a clear, colourless solution, in a flexible polyester bag with an aluminium over pouch. Each bag contains 100 ml or 200 ml solution. It is supplied in packs of 5 bags of the 100 ml or 200 ml solution or 24 or 60 bags of the 100 ml solution and 12 or 32 bags of the 200 ml solution. Not all pack sizes may be marketed.

Marketing Authorisation Holder

In the UK: AbbVie Ltd, AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, SL6 4UB, United Kingdom

In Ireland: AbbVie Limited, Citywest Business Campus, Dublin 24, Ireland

Manufacturer

Baxter Healthcare S.A, Moneen Road, Castlebar, Ireland

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

Chirocaine: Italy, Sweden, Netherlands, France, UK, Ireland, Finland, Greece, Belgium, Luxembourg.

Chirocaine: Spain

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Detailed information on this medicine is available from the following website:

Ireland: www.hpra.ie

Chirocaine 1.25 mg/ml solution for infusion.

Instructions for use and handling

Chirocaine 1.25 mg/ml solution for infusion 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.

Shelf life after dilution in sodium chloride solution 0.9%:

Chemical and physical in-use stability has been demonstrated for levobupivacaine 1.25 mg/ml with 8.3-8.4 µg/ml clonidine, 50 µg /ml morphine and 2 µg /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 levobupivacaine 1.25 mg/ml with sufentanil added in the concentration of 0.4 µg /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 admix has been prepared in controlled and validated aseptic conditions.

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

Chirocaine 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.

Chirocaine 1.25mg/ml solution for infusion is packaged in an integral foil overpouch. Inside the integral foil overpouch there is a gradient in relative humidity between that of the solution bag headspace and the space between the bag and overpouch. Due to this phenomenon, a small amount of condensation or water beadlets between the foil overpouch and the bag surfaces may be observed on opening the foil overpouch. This is considered normal for this product. In line with the product user instructions for parenteral medicinal products, the primary bag should be checked for leaks on removal of the overpouch. If a leak is confirmed, discard the solution bag, as the sterility of solution may be impaired.

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.