

CR No.:	CR-0001769-2014	Customer:	Campoverde	Min. text size: 8 pt	
Commodity No.:	20002632	Product name/Country:	Chirocaine 2.5 mg/ml, 5.0 mg/ml / GB/IE	Colors:	Black
Draft No.:	3	Size:	330 x 270 mm, folded 85 x 135 mm		
Revision date:	18. Dec. 2014	Paper:	50 g/mq, presence of perforated line		
Graphic Artist:	G. Tittes	Pharma code:	IXXI (21)		

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**Package leaflet: Information for the user**

Chirocaine® 2.5 mg/ml and 5.0 mg/ml solution for injection/concentrate for solution for infusion Levobupivacaine

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist or nurse.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse. 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.

Adults:

Chirocaine is used as a local anaesthetic to numb parts of the body before major surgery (for example as an epidural for caesarean section) and minor surgery (such as on the eye and mouth).

It is also used for pain relief:

- after major surgery
- during childbirth

Children:

Chirocaine can also be used with children to numb parts of the body before surgery and for pain relief after minor surgery, such as the repair of a groin hernia. Chirocaine has not been tested in children less than 6 months of age.

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**2. What you need to know before you use Chirocaine****Do not use 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, pharmacist 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 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 Chirocaine:

Tell your doctor, pharmacist or nurse if you are taking, using 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 and breastfeeding

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

Chirocaine 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 Chirocaine on the child during the early stages 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.

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

Chirocaine 2.5 mg/ml or 5.0 mg/ml solution for injection/concentrate for solution for infusion.

Instructions for use and handling

Chirocaine 2.5mg/ml or 5.0mg/ml solution for injection/concentrate for solution for 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.

A sterile blister container should be chosen when a sterile ampoule surface is required. Ampoule surface is not sterile if sterile blister is pierced.

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.

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.

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. Breastfeeding 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 3.6 mg/mL sodium in the bag or ampoule solution to be taken into consideration by patients on a controlled sodium diet.

3. How to use Chirocaine

Your doctor will give you Chirocaine by injection through a needle or into a small tube in your back (epidural). Chirocaine 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 Chirocaine.

Dosage

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 labour or for childbirth by caesarean section (an epidural), the dose used should be particularly carefully controlled.

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, pharmacist or nurse.

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 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.

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
- heart block or heart stopping
- 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, pharmacist 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 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 Chirocaine contains

The active substance is levobupivacaine (as hydrochloride).

Chirocaine 2.5 mg/ml solution for injection/concentrate for solution for infusion: One ml contains 2.5 mg levobupivacaine (as hydrochloride). Each ampoule contains 25 mg in 10 ml.

Chirocaine 5 mg/ml solution for injection/concentrate for solution for infusion: One ml contains 5 mg levobupivacaine (as hydrochloride). Each ampoule contains 50 mg in 10 ml.

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

What Chirocaine looks like and contents of the pack

Chirocaine Solution for injection / concentrate for solution for infusion is available in strengths containing 2.5 mg or 5.0 mg of levobupivacaine per ml. It is a clear, colourless solution, in polypropylene ampoules. Each ampoule contains 25 mg or 50 mg levobupivacaine in a 10 ml ampoule. It is supplied in packs of 5, 10 or 20 ampoules.

Marketing Authorisation Holder

United Kingdom

AbbVie Ltd
Abbott House
Vanwall Road
Vanwall Business Park
Maidenhead
Berkshire
SL6 4XE

Ireland

AbbVie Limited
Block B
Liffey Valley Office Campus
Quarryvale,
Co. Dublin
Ireland

Manufacturer

AbbVie S.r.l., S.R. 148 Pontina km 52 s.n.c., 04011 Campoverde di Aprilia (LT), Italy

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

Chirocaine: Sweden, Portugal, Switzerland, Latvia, Netherlands, Poland, France, UK, Ireland, Finland, Greece, Slovenia, Austria, Belgium, Hungary, Bulgaria, Czech Republic, Luxembourg

Chirocane: Spain

This leaflet was last revised in November 2014

Detailed information on this medicine is available from the websites below:

United Kingdom: www.mhra.gov.uk

Ireland: www.hpra.ie

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CHIROCAINE®
LEVOBUPIVACAINE HCL
2.5 mg/ml AND 5.0 mg/ml

ADMINISTRATORS' INSTRUCTIONS



- 1** Read the label carefully. Shake down any contents from the neck.



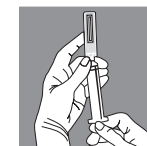
- 2** Hold ampoule in palm of hand waist height. Hold arrow on ampoule held between thumb and forefinger (thumb away from you). TWIST QUICKLY AND SHARPLY TOWARDS YOU (anti-clockwise).



- 3** Push firmly the tapered luer tip of syringe into ampoule.



- 4 - 5** Gently push the ampoule towards you with the forefinger and withdraw the content slowly, taking special care at first.



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