

CHIROCAINE

SOLUTION FOR INJECTION & CONCENTRATED SOLUTION FOR INFUSION

levobupivacaine 25mg/10mL, 50mg/10mL, 75 mg/10mL, 62.5mg/100mL*, 125mg/100mL*, 250mg/200mL

CONSUMER MEDICINE INFORMATION

PLEASE READ THIS INFORMATION CAREFULLY

What is in this leaflet?

This leaflet answers some common questions about this medicine.

It does not contain all of the available information. It does not take the place of talking to your doctor.

All medicines have benefits and risks. Your doctor has weighed the risks associated with giving you CHIROCAINE against the benefits he/she expects it will have on you.

If you have any concerns about taking this medicine, talk to your doctor, pharmacist or nurse.

Keep this leaflet while you are being given CHIROCAINE. You may need to read it again.

What CHIROCAINE is used for

CHIROCAINE is used to anaesthetise (numb) or make free from pain, specific parts or areas of the body before minor surgery (including surgery to the eye and mouth), and major surgery (including having a baby by caesarean section). CHIROCAINE is also used to help relieve pain during labour and childbirth and after an operation.

Your doctor, however, may have prescribed CHIROCAINE for another purpose. Ask your doctor if you have any questions about why

CHIROCAINE has been prescribed for you.

CHIROCAINE belongs to the group of medicines called local anaesthetics. These medicines work by making an area of the body numb or free from pain.

CHIROCAINE is available only with a doctor's prescription.

Before you are given CHIROCAINE

You should not be given CHIROCAINE if:

You have ever had an allergic reaction to CHIROCAINE or any other anaesthetic. Some of the symptoms of an allergic reaction may include rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty in breathing.

Before you start to take or are given CHIROCAINE you must tell your doctor if

1. You are pregnant or plan to become pregnant. Your doctor will discuss the risks and benefits of receiving CHIROCAINE when pregnant;
2. You are breastfeeding or wish to breastfeed. Your doctor will discuss the risks and benefits of

receiving CHIROCAINE when breastfeeding;

3. You have, or have had any medical conditions including:
 - Kidney or liver disease
 - Heart disease
 - Very low blood pressure
 - Difficulties with blood clotting
 - Conditions affecting the nervous system (neurological problems)
 - An electrolyte imbalance (unusual amount of salt in your body)
 - A condition called hypoxia (lack of oxygen in your blood)
4. You are allergic to any other medicines, foods, dyes or preservatives.

If you have not told your doctor or nurse about any of the above, tell them before you are given CHIROCAINE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop. In particular, tell your doctor if you take any of the following:

- Local anaesthetics or drugs that are related to amide-type local anaesthetics eg lignocaine
- Medicines used for epilepsy:
 - phenytoin

- phenobarbitone
- Medicines used to treat tuberculosis
- rifampicin
- Azole antimicrobials :
 - ketoconazole
- Anti-HIV medicines:
 - ritonavir
- Macrolide antibiotics: erythromycin
- clarithromycin
- Calcium channel antagonists:
 - verapamil
- Medicines to treat stomach problems:
 - omeprazole
 - cimetidine
- Antidepressants:
 - fluvoxamine
- Medicines to treat heart problems:
 - mexilitine

These medicines may affect how well CHIROCAINE works, or may be affected by CHIROCAINE. Your doctor or pharmacist can tell you what to do if you are receiving CHIROCAINE at the same time as you are taking other medicines.

How CHIROCAINE is given

Your doctor or nurse will administer CHIROCAINE, usually by injection through a needle or into a small tube in your back (epidural).

While being given CHIROCAINE, you should drink plenty of fluids or, if you are unable to drink, your doctor will make sure that you receive plenty of fluids.

Your doctor will determine how CHIROCAINE will be given and when it will be given. This may differ from the information contained in this leaflet.

How much will be given?

The dosage for both adults and children will depend on the condition you are being treated for, on your body weight and on your medical condition.

The smallest dose that can produce an effective anaesthesia (numbing of the required area) will be used.

Your doctor will adjust the amount or frequency of your doses according to the degree of numbness required.

If there is something that you do not understand, please ask your doctor, pharmacist or nurse for help.

If you are given too much CHIROCAINE

As CHIROCAINE is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects after being given CHIROCAINE tell your doctor immediately. You may need urgent medical attention.

While you are being given CHIROCAINE

Things you must do

- Always follow your doctor's instructions carefully
- Tell your doctor if you become pregnant while being given CHIROCAINE
- If you are about to start taking a new medicine, tell your doctor, pharmacist or nurse that you are taking CHIROCAINE
- It is important that you drink a lot of water while receiving CHIROCAINE to help remove the drug from your system.

Things to be careful of

Be careful driving or operating machinery until you know how CHIROCAINE affects you. CHIROCAINE may cause dizziness

or light-headedness in some people. Tell your doctor if this happens.

How long is CHIROCAINE given for?

Your doctor will tell you for how long you will be given CHIROCAINE. Even if you feel better or improve after a few days, your doctor may continue to give you CHIROCAINE.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given CHIROCAINE.

CHIROCAINE is used to anaesthetise (numb) specific parts or areas of the body.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor, pharmacist or nurse to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- Light-headedness
- Dizziness
- Blurred vision
- Muscle twitching
- High temperature
- Numbness or tingling of the skin
- Low blood pressure
- Fast or slow heart beat
- Weakness

Tell your doctor immediately if you notice any of the following:

- Difficulty breathing, rashes, pain and muscle spasm
- A change in the amount or frequency of urine passed, blood in the urine or pain on urination;

- Bleeding or bruising more easily than normal, reddish or purplish blotches under the skin;
- Hearing loss, dizziness, ringing in the ears, loss of balance, lightheadedness;
- Redness or swelling at the site of injection;
- Swelling to the face, lips, mouth, throat or neck which may cause difficulty in swallowing or breathing;
- Seizures

After you have finished being given CHIROCAINE

Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with CHIROCAINE:

- Head ache or back ache after an epidural injection. This may not always be related to the medicine used.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything that is making you feel unwell while you are being given, or soon after finishing, CHIROCAINE, even if it is not on this list.

Storage

CHIROCAINE is stored in the pharmacy or on the ward. The injection is kept in a cool dry place and protected from light.

The bags are stored below 25°C.

The ampoules are stored below 30°C

Product Description

What it looks like

CHIROCAINE is available in three strengths. 2.5mg, 5.0mg and 7.5mg of clear, colourless levobupivacaine per mL of solution, in plastic ampoules as well as 62.5mg/100mL*, 125mg/100mL* and 250mg/200mL flexible infusion bags that are overwrapped in an aluminium foil pouch.

Active Ingredients

For Chirocaine 25mg/10mL:

Each ampoule contains 25mg levobupivacaine as levobupivacaine hydrochloride

For Chirocaine 50mg/10mL:

Each ampoule contains 50mg levobupivacaine as levobupivacaine hydrochloride.

For Chirocaine 75mg/10mL:

Each ampoule contains 75mg levobupivacaine as levobupivacaine hydrochloride.

For Chirocaine 62.5mg/100mL*:

Each bag contains 62.5mg levobupivacaine as levobupivacaine hydrochloride

For Chirocaine 125mg/100mL*:

Each bag contains 125mg levobupivacaine as levobupivacaine hydrochloride

For Chirocaine 250mg/200mL:

Each bag contains 250mg levobupivacaine as levobupivacaine hydrochloride

CHIROCAINE also contains water and small amount of sodium chloride, sodium hydroxide and hydrochloric acid.

Supplier

AbbVie Pty Ltd
241 O'Riordan Street
Mascot NSW 2020
Australia

Australian registration numbers:

CHIROCAINE levobupivacaine 25mg/10mL -

AUST R 76815

CHIROCAINE levobupivacaine 50mg/10mL -

AUST R 76862

CHIROCAINE levobupivacaine 75mg/10mL -

AUST R 76864

CHIROCAINE levobupivacaine 62.5mg/100mL -

AUST R 94479*

CHIROCAINE levobupivacaine 125mg/100mL -

AUST R 94480*

CHIROCAINE levobupivacaine 250mg/200mL -

AUST R 94482

* Not marketed in Australia

Date of this Text:

05 January 2016

Version 10