

PACKAGE LEAFLET: INFORMATION FOR THE USER

Librium 5 mg and 10 mg Capsules

Chlordiazepoxide hydrochloride

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, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Librium is and what it is used for
2. What you need to know before you take Librium Capsules
3. How to take Librium Capsules
4. Possible side effects
5. How to store Librium Capsules
6. Contents of the pack and other information

1. WHAT LIBRIUM IS AND WHAT IT IS USED FOR

Librium belongs to a group of medicines known as benzodiazepines, which are tranquillisers (medicines that have a calming effect).

Librium capsules are used for the short-term treatment of severe anxiety, which may occur alone or in association with sleeplessness (insomnia) or personality/behavioural disorders. Librium capsules may also be used to treat muscle spasms, and to relieve symptoms of sudden alcohol withdrawal.

You must talk to a doctor if you do not feel better or if you feel worse.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE**LIBRIUM CAPSULES****Do not take Librium:**

- If you are allergic to chlordiazepoxide or any of the ingredients of this medicine (listed in section 6).
- If you are allergic (hypersensitive) to any medicine known as a benzodiazepine (e.g. nitrazepam, diazepam, flurazepam, or temazepam).
- If you suffer from lung disease.
- If you suffer with breathing difficulties while awake or asleep.
- If you suffer from myasthenia gravis (a condition in which the muscles become weak and tire easily).
- If you are suffering from a psychiatric illness or a personality disorder (severe mental problems).
- If you have a severe liver condition.
- If you have spinal or cerebral ataxia

Warnings and precautions

Talk to your doctor or pharmacist before taking Librium if:

- You have a long-term lung, liver or kidney disease.
- You suffer from depression or have recently suffered the death of a close friend or relative.
- You are suffering or have suffered from a mental illness.
- You have abused alcohol or drugs.
- You are pregnant or breast feeding.
- You have a decrease in mental function as you should receive a lower dose.

Librium capsules relax the muscles, therefore elderly patients should take extra care when they get up at night as there is a risk of falls and consequently of injuries including hip fractures.

Children and adolescents

Librium Capsules are not to be used in anyone under 18 years of age.

Other medicines and Librium

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is extremely important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines involved. In particular, tell your doctor if you are taking any of the following medicines:

- Antidepressants, sleeping tablets, neuroleptics, hypnotics, tranquillisers (may increase effects of relaxing muscles – higher risk of falling in elderly patients) or other such medicines which act on the brain and nerves.
- Medicines used to relieve pain or anaesthetics.
- Antihistamines (used for treating allergies) that cause drowsiness (e.g. chlorphenamine)
- Medicines for treating epilepsy (e.g. phenytoin and phenobarbital).
- Medicines that affect the liver (e.g. the antibiotic rifampicin and cimetidine, omeprazole, macrolide antibiotics (erythromycin); medicines used to treat stomach problems, disulfiram and contraceptive agents).
- Medicines used to treat viral infections (e.g. ritonavir) as these medicines can potentiate the actions of benzodiazepines.
- Drugs to treat high blood pressure (e.g. beta blockers, anticoagulants, cardiac glycosides, moxonidine).

- Drugs known as dopaminergics (e.g. levodopa, for Parkinson's disease).
- Sodium oxybate used in patients with narcolepsy (possible increase of respiratory depression)
- Theophylline; drug to make breathing easier

Concomitant use of Librium Capsules and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe Librium Capsules together with opioids the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Librium with food, drink and alcohol

Take the medicine before or with your meals.

Do not drink alcohol for as long as you are taking Librium Capsules.

Alcohol will increase the effects of the capsules and this can be dangerous.

Pregnancy, breast-feeding and fertility

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

Avoid use of Librium if you are breast-feeding, as Librium passes into breast-milk.

If your doctor has decided that you should receive this medicine during late pregnancy or during labour, your baby might have a low body temperature, floppiness and breathing and feeding difficulties. Also, your unborn baby may be at risk of developing dependency to this medicine and after birth may be at some risk of developing withdrawal symptoms.

Driving and using machines

Librium Capsules may cause side effects such as drowsiness, tiredness, dizziness, confusion, poor muscle co-ordination and problems with your eyesight. This may affect your ability to drive and operate machinery. Do not drive or operate machinery if you experience any of these side effects.

The medicine can affect your ability to drive. Do not drive while taking this medicine until you know how it affects you.

It may be an offence to drive if your ability to drive safely is affected. However, you would not be committing an offence if:

The medicine has been prescribed to treat a medical or dental problem and

- You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
- It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

There is further information for patients who are intending to drive in Great Britain – go to <https://www.gov.uk/drug-driving-law>

Librium contains

Librium Capsules contain lactose. Therefore, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE LIBRIUM CAPSULES

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will find the lowest dose to control your symptoms. The dose that your doctor prescribes will depend on the nature of your illness, your reaction to the medicine, your age and bodyweight.

If you think that the effect of your medicine is too weak or too strong, talk to your doctor.

Dosage

For the treatment of:	Usual dosage:
Anxiety	Up to 30 mg per day. The maximum dose is 100 mg per day, taken in divided doses throughout the day
Sleeplessness (Insomnia) associated with anxiety	10 to 30 mg before going to sleep.



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Symptoms of sudden alcohol withdrawal	25 to 100 mg. This can be repeated 2 to 4 hours after the initial dose, if necessary
Muscle spasms	10 to 30 mg per day, taken in divided doses throughout the day.

If you are elderly or suffer from a lung, liver or kidney condition, or are generally unwell, your doctor will usually prescribe a lower dose.

Use in children and adolescents

Librium Capsules are not to be used in anyone under 18 years of age.

Swallow the capsule(s) whole with a glass of water.

You will normally see an improvement in your symptoms after 10 to 15 days of taking Librium regularly.

Treatment will not normally be continued for more than 4 weeks. This is because Librium Capsules may become less effective if you take them for more than four weeks. If you think that your medicine is no longer working, you should consult your doctor.

Also, you may become dependent on the capsules if you use them at high doses and for long periods. Therefore, Librium Capsules are not suitable for long-term use and after a few weeks it is worth trying to get by without these capsules. This will help to prevent you becoming used to Librium and reduce the risk of dependence.

Do not stop taking Librium Capsules without discussing with your doctor (refer to "If you stop taking Librium" below.)

If you take more Librium than you should

If you take too many capsules or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away.

If you forget to take Librium

Do not take a double dose to make up for a forgotten dose. Instead you should simply continue with the next dose when it is due.

If you stop taking Librium

Your doctor will advise you when to stop taking the capsules. Do not stop taking Librium Capsules abruptly. You may experience withdrawal effects if your treatment is stopped suddenly. This is less likely if your dose is gradually reduced towards the end of your treatment.

Withdrawal symptoms may include:

- A recurrence of sleep problems
- Depression
- Nervousness
- Irritability
- Sweating
- Extreme anxiety
- Diarrhoea
- Confusion
- Restlessness
- Incontinence
- Headaches
- Muscle pain

In severe cases the following symptoms may occur:

- changes in behaviour or the way you are feeling
- numbness and tingling of the extremities
- over-sensitivity to light, noise and touch
- hallucinations
- fits

If you are woken up soon after taking the medicine your memory may be temporarily affected.

If you have taken benzodiazepines for a long time, the reduction in your dosage will be over a longer period of time than would normally be required when you stop taking this medicine. You may need additional help.

Your doctor will be able to discuss this with you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

It is very important that you immediately seek medical advice if you develop any of the following symptoms:

A severe allergic (anaphylaxis) or serious allergic reaction which causes swelling of your face or throat (angioedema), difficulty breathing, thoughts of self-harm, yellowing of the eyes and skin (jaundice), abnormality in the blood (blood dyscrasias) with symptoms such as weakness, pale skin, bleeding problems, sore throat and frequent infections.

Changes in behaviour may occur rarely. These changes may include aggression, excitement, confusion and depression.

If these behavioural symptoms occur, you must inform your doctor.

He/she may want you to stop taking this medicine.

Tell your doctor or pharmacist if you develop any of the following side effects:

Common:

- drowsiness and light headedness the next day
- tiredness
- sedation and dizziness
- loss of balance
- unsteadiness and clumsiness
- poor muscle co-ordination
- confusional states
- speech disorder

Rare:

- headache
- vertigo
- low blood pressure
- stomach upsets
- skin rashes
- problems with your eyesight
- emotional disturbances
- double vision
- changes in the level of sexual desire
- inability to pass urine
- incontinence
- impotence
- menstrual disorder

The following side effects have also been reported

(Frequency unknown):

- Forgetfulness, memory loss, hallucinations, dependence, depression, restlessness, agitation, irritability, aggression, delusion, nightmares, changes in salivation, increased liver enzymes, changes in the way you walk and muscle weakness.
- Paradoxical reactions (e.g. anxiety, sleep disorders, insomnia, suicide attempt, suicidal ideation).
- Tremor, stiffness and slow movement. If you are woken up soon after taking the medicine your memory may be temporarily affected.
- Increased appetite

If you are an elderly patient, you may be more susceptible to side effects and may suffer from confusion. If this happens, tell your doctor and he/she may decide to change your dose.

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 at: 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 LIBRIUM CAPSULES

- Keep this medicine out of the sight and reach of children.
- Do not use Librium Capsules after the expiry date which is stated on the bottle and outer carton after "EXP". The expiry date refers to the last day of that month.
- Store Librium Capsules below 30°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Librium contains

Active substance: Chlordiazepoxide hydrochloride. Each capsule contains 5 mg or 10 mg of chlordiazepoxide hydrochloride.

Other ingredients: Starch maize white, talc purified, lactose, gelatine and the colouring agents yellow iron oxide (E172), indigo carmine (E132) and titanium dioxide (E171). In addition, the 5 mg capsules also contain the colouring agents quinolone yellow (E104) and erythrosine (E127).

What Librium looks like and contents of the pack

- Librium 5 mg Capsules are green and yellow with "LIB 5" printed on them.
- Librium 10 mg Capsules are black and green with "LIB 10" printed on them.
- Librium Capsules are available in pack sizes of 100.

Marketing Authorisation Holder and Manufacturer

Mylan Products Ltd,
Station Close, Potters Bar, Hertfordshire, EN6 1TL, UK

Manufacturer

Labiana Pharmaceuticals S.L.U., Casanova 27-31
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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