

Package leaflet: Information for the user

Librium Librium 5 mg Hard Capsules Librium 10 mg Hard 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 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.

The name of your medicine is Librium 5 mg and 10 mg Hard Capsules, which will be called Librium capsules throughout this leaflet.

What is in this leaflet:

1. What Librium capsules are and what they are 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 CAPSULES ARE AND WHAT THEY ARE USED FOR

Librium capsules contain the active ingredient chlordiazepoxide hydrochloride, which belongs to a group of medicines called benzodiazepines.

Librium capsules are used:

- For the short-term (2-4 weeks) treatment of severe anxiety, which may occur alone or in association with sleeplessness (insomnia) or personality/behavioural disorders.
- To control muscle spasm
- In the management of alcohol withdrawal

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LIBRIUM CAPSULES

Do not take Librium capsules:

- If you have a condition called myasthenia gravis
- If you have severe breathing difficulties
- If you have sleep apnoea syndrome (breathing problems when asleep)
- If you have severe liver disease
- If you suffer from spinal or cerebral ataxia (loss of full control of bodily movements)
- If you are allergic to chlordiazepoxide, other similar drugs (benzodiazepines), or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Warnings and precautions

Talk to your doctor or pharmacist before taking Librium capsules:

- If you have a history of alcohol or drug abuse
- If you intend to stop taking Librium capsules

- If you develop withdrawal symptoms, e.g. depression, headaches, muscle pain, muscle weakness, extreme anxiety, nervousness, tension, restlessness, confusion, mood changes, rebound insomnia, sweating, diarrhoea and irritability
- If you may experience loss of memory. This usually occurs several hours after taking the capsules, therefore they should be taken at night before sleep.
- If your behaviour changes, e.g. you become angry or agitated or have strange thoughts
- If you have breathing problems
- If you have liver disease
- If you are mentally unwell or suffer from a personality disorder
- If you suffer from depression or anxiety or have a psychotic illness

Librium capsules may become less effective with repeated use. You may also become dependent on Librium capsules, especially if you have a history of drug or alcohol abuse.

Other medicines and Librium capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you take these capsules with some other medicines, the effect of these capsules or the other medicine may be changed, tell your doctor or pharmacist if you are taking drugs that have an effect on the brain – examples of these are:

- Strong painkillers
- Medicines used to treat mental illness
- Sedatives
- Tranquilizers
- Medicines used to treat epilepsy
- Anaesthetics
- Antidepressants
- Medicines used to treat anxiety
- Sleeping tablets
- Antihistamines that make you sleepy
- Medicines that affect liver enzymes (e.g. cimetidine, omeprazole)

It may still be all right for you to be given Librium capsules and your doctor will be able to decide what is suitable for you.

Concomitant use of Librium 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 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 capsules with alcohol

Do not drink alcohol whilst taking these capsules, as it may enhance the sedative effect.

Pregnancy and breast-feeding

You should not take Librium capsules while pregnant or breast-feeding as it might harm the baby. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Librium capsules may cause sleepiness, amnesia (loss of memory), poor concentration, poor co-ordination and may also modify performance of skilled tasks. These effects are more likely if you do not get enough sleep or drink alcohol. If you develop any of these symptoms you should not drive or operate machinery.

Librium capsules contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Librium capsules.

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.

The recommended doses are as follows:

Adults

Anxiety and muscle spasm: the total daily dose is 30 mg in divided doses. In severe cases, this may be increased to 40 to 100 mg in divided doses. Management of symptoms of alcohol withdrawal: The usual dose range is 25 to 100 mg repeated 2 to 4 hours if necessary.

Older People

The dose should be half of the adult dose in older people or in the weak and infirm.

Special patient groups: if you have long term breathing problems, your dose will be reduced.

Use in Children

Use in children is not recommended.

If you take more Librium capsules than you should

Go to the accident and emergency department of your hospital immediately. Signs of overdose are sleepiness, confusion, and tiredness. In more severe cases, shallow breathing, unresponsiveness, and coma can occur.

If you stop taking Librium capsules

You should not stop taking Librium capsules without telling your doctor.

If you stop taking Librium capsules you may suffer from withdrawal symptoms such as headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability.

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.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported:

Common (may affect up to 1 in 10 people):

- Sedation,
- dizziness,
- somnolence,
- ataxia,
- balance disorder,
- confusional state,
- fatigue.

Rare (may affect up to 1 in 1,000 people):

- bone marrow depression,
- headache,
- vertigo,
- visual impairment,
- low blood pressure,
- gastrointestinal disorder,
- skin reaction (e.g. rash),
- urinary retention,
- libido disorder,
- erectile dysfunction,
- menstrual disorder.

Not known (frequency cannot be estimated from the available data):

- hypersensitivity,
- increased appetite,
- amnesia (loss of memory), hallucination, dependence depression,
- restlessness, agitation, irritability,
- depressed level of consciousness (reduced alertness),
- aggression, delusion, nightmares, psychotic disorders, abnormal behaviour, emotional disturbances,
- paradoxical drug reaction (e.g. anxiety, sleep disorders, insomnia, suicide attempts and ideation, difficulties with speech,
- gait disturbance, extrapyramidal disorder (e.g. tremor),
- respiratory depression,
- jaundice, increased level of bilirubin in the blood, increased levels of transaminases, increased levels of alkaline phosphate in the blood,
- muscle weakness.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie. 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 this medicine after the expiry date which is stated on the carton and the bottle after "EXP". The expiry date refers to the last day of that month.

Librium 5mg Capsules: Do not store above 30° C.

Librium 10mg Capsules: Do not store above 25° C.

Keep the bottle in the outer carton in order to protect from light.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Librium capsules contain:

- The active substance is chlordiazepoxide hydrochloride. Each capsule contains 5 mg or 10 mg of the active substance.
- The other ingredients are: gelatin, maize starch, talc, lactose monohydrate, titanium dioxide (E171), yellow iron oxide (E172), indigo carmine (E132) and red iron oxide (E172).
- Librium 5mg capsules also contain: quinolone yellow (E104) and erythrosine (E127).
- Librium 10mg capsules also contain: black iron oxide (E172).

What Librium capsules look like and contents of the pack

Librium 5 mg capsules are hard capsules having a yellow body and a green cap, imprinted with the monogram 'LIB 5' in red-brown and containing a white to off-white powder.

Librium 10 mg capsules are hard capsules having a green body and a black cap, imprinted with the monogram 'LIB10' in red-brown and containing a white to off-white powder.

Librium capsules come in an amber glass screw cap bottle containing 100 capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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