LIBRIUM 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 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 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 un-born 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 to drive while 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:

<table>
<thead>
<tr>
<th>Psychiatry (e.g. agitation, restlessness, insomnia), associated with anxiety</th>
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<tr>
<td>Up to 30 mg per day. The maximum dose is 100 mg per day, taken in divided doses throughout the day</td>
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<td>10 to 30 mg before going to sleep</td>
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Alcohol will increase the effects of the capsules and this can be dangerous.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist before taking this medicine.

Medicines used to treat viral infections (e.g. ritonavir) as these medicines may also be used to treat muscle spasms, and to relieve symptoms of sudden personality/behavioural disorders. Librium capsules are used for the short-term treatment of severe anxiety, which are tranquillisers (medicines that have a calming effect).

If you are allergic to any medicine known as a benzodiazepine, antihistamines (used for treating allergies) that cause drowsiness, antihypertensives, medicines that have a calming effect.

If you are allergic to chlordiazepoxide or any of the ingredients of this medicine (listed in section 6). If you are allergic to chlordiazepoxide or any of the ingredients of this medicine (listed in section 6).

If 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.

Librium 5 mg and 10 mg Capsules
Chlordiazepoxide hydrochloride
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 too many 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 may 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 pharmacist.

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 quinoline 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
08757 - Corbera de Llobregat (Barcelona), Spain

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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Important:

You may want you to stop taking this medicine.

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

- 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

Rarer:

- 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
- Muscle weakness

Muscle spasms 10 to 30 mg per day, taken in divided doses throughout the day.