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.

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 severe liver condition.
- If you suffer from myasthenia gravis (a condition in which the muscles become weak and tire easily).
- If you suffer from a mental health condition that might affect your ability to drive (e.g. schizophrenia, manic behaviour, or bipolar disorder).
- If you have a mental illness.
- If you are suffering from depression or have recently suffered the death of a close friend or relative.
- If 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.
- If you have taken more than one medicine at the same time.
- If you are allergic to chlordiazepoxide or any of the ingredients of this medicine.

Other medicines and Librium

You may take other medicines. However, you may need to take 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.

3. HOW TO TAKE LIBRIUM CAPSULES

Always take this medicine exactly as your doctor has told you. Do not take more than the total daily dose.

Dosage

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

4. POSSIBLE SIDE EFFECTS

Side effects may include:
- Drowsiness
- Tiredness
- Dizziness
- Confusion
- Poor muscle co-ordination
- Problems with your eyesight.

Driving and using machines

Do not drive or use 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.

5. HOW TO STORE LIBRIUM CAPSULES

Store in a cool, dry place.

For more information, talk to your doctor or pharmacist.
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 4 weeks. If you think that your medicine is no longer working, you should consult your doctor. Also, you may become dependent on the capsul 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
- muscle pain
- incontinence
- confusion
- diarrhoea
- extreme anxiety
- tiredness
- drowsiness and light headedness the next day

**Rare:**
- speech disorder
- nervousness
- depression
- A recurrence of sleep problems
- fits
- hallucinations
- dependence, depression, loss of balance, unsteadiness and clumsiness
- poor muscle co-ordination
- confusion
- poisons with your eyesight
- emotional disturbances
- changes in the level of sexual desire
- inability to pass urine
- 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

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 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**
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**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.
This leaflet was last revised in May 2016