

PACKAGE LEAFLET: Information for the patient

LIBRIAN

Sugar-coated tablets – 10 mg

(Chlordiazepoxide)

Read this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Librian is and what it is used for
2. Before you take Librian
3. How to take Librian
4. Possible side effects
5. How to store Librian
6. Other information

1. WHAT LIBRIAN IS AND WHAT IT IS USED FOR

Librian contains the active substance chlordiazepoxide, which like all other benzodiazepines, potentiates the effects of the gamma-aminobutyric acid (GABA) (facilitates the inhibitory neurotransmission of GABA) and of the other inhibitory neurotransmitters, by binding with the specific benzodiazepinic receptors. The potentiation of the effects of GABA causes the inhibition of the central nervous system.

Librian is almost completely absorbed after oral administration. It is highly bound (about 96%) to plasmatic proteins, while its elimination half-life is from 5 to 30 hours. Chlordiazepoxide passes in the cerebrospinal fluid and in breast milk, as also in the placenta. Metabolites

pharmacologically active of chlordiazepoxide are: desmethylchlordiazepoxide, demoxepam, desmethyldiazepam and oxazepam. The unchanged drug and the metabolites are excreted through urine, mainly as conjugated metabolites.

Librian sugar-coated tablets are used in the:

- short-term treatment of severe conditions of anxiety and tension, which occur alone or accompanied with insomnia or organic disorders;
- treatment of muscular spasms with a psychogen and neurogen origin;
- relief of symptoms from acute alcohol withdrawal;
- relief of concerns and anxiety before surgical interventions.

2. BEFORE YOU TAKE LIBRIAN

Do not take Librian:

- if you are sensitive (allergic) to chlordiazepoxide, to benzodiazepines in general or to any of the other excipients of Librian sugar-coated tablet;
- if you have acute respiratory failure;
- if you have severe hepatic disorders;
- in the sleep apnea syndrome;
- in chronic psychosis;
- if you have acute toxicity with alcohol;
- if you are in a comatose condition; shock condition;
- in phobic or obsessive conditions;
- in closed angle glaucoma;
- in *Myasthenia gravis*;

Librian should not be used alone in the treatment of depression or anxiety associated with depression.

Take special care with Librian

Librian should be used with special care in:

- patients with renal and hepatic disorders;
- respiratory diseases;
- the elderly;

- depressed patients with a suicidal tendency;
- patients with muscle weakness;
- patients with personality disorders;
- patients with organic alterations of the brain.

During treatment with chlordiazepoxide, like also with all the other benzodiazepines, a psychic and physical pharmacodependence may appear. The factors that influence the manifestation of dependence are: treatment duration, dosage, combination with psychotropic substances, anxiolytics, hypnotics, previous drug dependence.

The long-term treatment and the immediate withdrawal should be avoided.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Librian. Please contact your doctor or pharmacist if you are taking or have recently taken other drugs, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Librian if you have been given any other drug during treatment.

It is especially important that your doctor knows that you are being treated with:

- valproic acid, cimetidine, omeprazole, macrolide antibiotics (erythromycin), disulfiram, fluoxetine, isoniazid, ketoconazole, oral contraceptives, metoprolol, propoxyphene, propranolol, alcohol, barbiturates, narcotics, medicines used to relieve pain (e.g. codeine phosphat), anaesthetics (before you have any surgical operation tell your doctor you are taking chlordiazepoxide), sedative antihistamines (e.g. chlorphenamine), nabilone, antacids, probenecid, ranitidine, rifampicin, scopolamine and theophylline, because these influence the effect of benzodiazepines;
- digoxin, phenytoin, anticoagulants (e.g. warfarin), sodium oxybate, medicines to treat high blood pressure (e.g. methyldopa, ACE inhibitors, alpha blockers, angiotensin II receptor blockers, calcium channel blockers, moxonidine etc.), vasodilators (e.g. nitrates), diuretics (e.g. furosemid), levodopa and neuromuscular inhibitors, since these are influenced by benzodiazepines.

Taking Librian with food and drinks

Librian should not be taken with alcohol, because the combination with alcohol of

chlordiazepoxide, as also of the other benzodiazepines, manifests a psychic and physical pharmacodependence.

Pregnancy

Ask for the advice of your pharmacist or of the doctor before taking this drug.

It is advised to avoid the use of Librian during pregnancy, especially during the first and last trimester. The doctor will evaluate the risk / benefit factor.

Breastfeeding

Chlordiazepoxide passes into breast milk and therefore it should not be used during breastfeeding.

Driving and using machinery

Librian may cause drowsiness, disorientation, confusion and marked hypotension, which may damage the ability of the patient to drive and use machinery.

Important information about some of the excipients of Librian

This drug contains sucrose. If you have an intolerance to some sugars, contact your doctor before taking this drug.

This drug also contains sodium benzoate.

3. HOW TO TAKE LIBRIAN

Always take Librian as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of Librian are too strong or too weak, talk to your doctor or pharmacist.

The sugar-coated tablets should be swallowed with at least a glass of water.

You can take the sugar-coated tablets with or without food.

The dosage is as follows:

Anxiety, adults: 5 - 10 mg, 3 times daily, that may be increased if necessary to 20 mg, 3 or 4 times daily;

elderly or debilitated patients: 5 - 10 mg daily.

Muscle spasms: 10 - 30 mg daily, in divided doses.

Concern and anxiety before surgical interventions: 5 - 10 mg, in the days before the surgical intervention.

Acute alcohol withdrawal syndrome: 50 - 100 mg, that is repeated if necessary (the maximal dose is 250 mg daily).

However, the dose may need to be increased or reduced. Your doctor will advise you accordingly.

If you have taken more Librian

If you have taken more Librian than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

Librian should not be taken for a long time, because dependence to this drug occurs.

If you forget to take Librian

If you forget a dose (or more doses), take the next dose when it is time to take it usually.

Do not take a double dose (or higher) to make up for a forgotten dose (doses).

If you stop taking Librian

Do not stop the treatment without consulting the doctor.

The treatment should not be stopped immediately, but gradually, by reducing the dose.

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

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Librian may cause side effects, although not everybody manifests them. Sometimes they are serious, sometimes not. Do not get alarmed by this list of possible side effects. No one of them may appear to you.

The side effects that may appear are:

- in the cardiovascular system (cardiovascular collapse, hypertension, tachycardia, bradycardia, oedema);
- in the central nervous system (drowsiness, confusion, ataxia, dizziness, asthenia, apathia, memory impairment, disorientation, anterograde amnesia, headache, slurred speech, loss of the

voice, stiffness, coma, euphoria, irritation, hallucinations, depression, depressed level of consciousness, delusion, nightmares, daydreaming and paradoxal reactions, such as: anger, hostility to others, mania, insomnia, muscle spasms, anxiety, suicide attempt, suicidal ideation);

- in the gastrointestinal tract (constipation, diarrhea, dry mouth, nausea, anorexia, vomiting, increased appetite);
- hematological (blood dyscrasias including agranulocytosis, anemia, thrombocytopenia, leucopenia, neutropenia).

Blurred vision, exanthema, liver function tests disorders, hepatitis, jaundice, withdrawal / dependence syndrome, anaphylactic reactions (that appear with angioedema, respiratory depression, etc.), muscle weakness (especially in the elderly), urinary retention, incontinence, menstrual disorders, libido disorders, erectile dysfunction, saliva altered have been noticed.

If any of the side effects worsens, or if you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE LIBRIAN

Keep out of the reach and sight of children!

Do not use Librian after the expiry date which is stated on the package.

Store below 25°C.

Store in the original packaging to protect from humidity.

6. OTHER INFORMATION

What Librian contains

The active substance is chlordiazepoxide.

Each sugar-coated tablet contains 10 mg chlordiazepoxide.

The excipients are: starch, microcrystalline cellulose, croscarmellose sodium, povidone, sodium starch glycolate, calcium carbonate, magnesium stearate, gelatin, talc, titanium dioxide, sucrose, quinoline yellow, indigo carmine, sodium benzoate, shellac, carnauba wax, beeswax white.

Content of the pack

Carton box with 30 sugar-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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