

LIORESAL

(Baclofen)

10 mg and 25 mg, tablets

Patient Information Leaflet

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LIORESAL 10 TABLETS

LIORESAL 25 TABLETS

Baclofen

Please read this leaflet carefully before using LIORESAL

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- LIORESAL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What this leaflet contains:

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

1. What LIORESAL is and what it is used for

What LIORESAL is

The active substance of LIORESAL tablets is baclofen.

What LIORESAL is used for

LIORESAL is one of a group of medicines called muscle relaxants.

LIORESAL is used to reduce and relieve the excessive tension (spasms) in your muscles occurring in various conditions such as multiple sclerosis, diseases or injuries of the spinal cord, and certain brain diseases.

Due to the relaxation of muscle and the consequent relief from pain, LIORESAL improves your ability to move, makes it easier for you to manage your daily activities and facilitates physiotherapy.

2. What you need to know before you take or use LIORESAL

BEFORE TAKING THE MEDICINE:

It is important to tell your doctor if you have other medical problems or if you are taking other medicines

Do not take LIORESAL

- **If you are allergic** to baclofen or any of the other ingredients of LIORESAL listed in section 6
- Porphyria

If you think you may be allergic, ask your doctor for advice

Take special care with LIORESAL

- **If you have** certain mental illnesses accompanied by confusion or depression.
- **If you are suffering from** epilepsy (seizures).
- **If you have** acute pain in your stomach (ulcer) or intestines, breathing problems, a kidney or liver disease, or a disturbance of circulation in your brain.
- **If you have** kidney disease. Your doctor will decide whether or not LIORESAL is the appropriate treatment for you
- **If you have** difficulty urinating.
- **If you are** diabetic.
- **If you have or had** depression, if you have been using alcohol excessively or if you had thoughts of killing yourself tell your doctor **before you take LIORESAL**.
- **If you have** thoughts of harming or killing yourself at any time, speak to your doctor straightaway or go to a hospital. Also, ask a relative or close friend to tell you if they are worried about any changes in your behavior and ask them to read this leaflet.
- If you are elderly or have muscle spasms caused by a brain disease. You may experience more side effects therefore your doctor will keep you under appropriate surveillance and may adapt the dose of LIORESAL you take.

If any of these apply to you, **tell your doctor before you take LIORESAL**.

Children and adolescents

Children's dosing is based on their body weight; the doctor will calculate the dose for the child.

Taking other medicines with LIORESAL

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. Remember also any medicines that were not prescribed by a doctor.

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines)

Substances known to interfere with the action of LIORESAL are:

- Alcohol may intensify the sedative effect of LIORESAL
- Sedative drugs may intensify the sedative effect of LIORESAL
- Medicines used to treat mood disorders such as antidepressants may intensify the effect of LIORESAL and weaken muscle tone and lithium may intensify uncontrolled body movements
- Medicines used to treat high blood pressure may result in a further decrease in blood pressure
- Medicines used to treat Parkinson's disease may intensify the adverse events associated with central nervous system as well as the symptoms of Parkinson's disease.
- Medicines for arthritis or pain may intensify the side effects of LIORESAL by weakening kidney function

Pregnancy, breastfeeding and fertility

You should not use LIORESAL during pregnancy.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machinery

Sedation, somnolence, drowsiness and fatigue may occur while you are taking LIORESAL. If this happens to you, do not drive a car, use a machine, or do other things that need your full attention.

3. How to take LIORESAL

How to use LIORESAL

Do not share medicines prescribed for you with any other person.

Always take LIORESAL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not exceed the recommended dose.

How much to take

Your doctor will tell you how long your treatment with LIORESAL will last. Do not stop treatment early because it might make you ill. If you have the impression that the effect of LIORESAL is too strong or too weak, tell your doctor or pharmacist.

Adults usually start treatment with 5 mg taken 3 times daily. The dose is then gradually increased until the best results are obtained; this may be between 30 mg to 80 mg per day, taken in 3 doses. Your doctor may even decide to give you a higher dosage.

Children's treatment is adjusted to their weight.

LIORESAL is always given in divided daily doses, i.e. usually 3 or 4 times a day. The dose prescribed by your doctor may be different from that written here. If this is the case, follow the doctor's instructions.

Your doctor will tell you exactly how many tablets of LIORESAL to take.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

When and how to take LIORESAL

Take LIORESAL during meals and swallow the tablets with some liquid. If necessary, the tablets may be broken.

Be sure to take this medicine regularly, and exactly as your doctor tells you. This will help you to get the best results and reduce the risk of side effects.

How long to take LIORESAL

If you have been treated for 6 to 8 weeks and you feel no improvement, tell your doctor. Your doctor will decide if you should continue LIORESAL.

If you forget to take LIORESAL

If you have forgotten to take one dose as scheduled, take it as soon as you remember. However, if it is almost time for your next dose, do not take a double dose to make up for forgotten individual doses. Just go back to your regular dosing timetable. If you have forgotten to take several doses you should contact your doctor.

If you take more LIORESAL than you should

In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

The main symptoms of overdose are drowsiness, breathing difficulties, trouble of consciousness and being unconscious (coma).

Other symptoms may include: feeling confused, hallucinations, agitation, convulsions, blurred vision, unusual muscle slackness, sudden contraction of the muscles, poor or absent reflexes, high or low blood pressure, slow or fast heartbeat, low body temperature, nausea, vomiting, diarrhoea or salivating a lot.

Effects when treatment with LIORESAL is stopped

Do not suddenly stop taking LIORESAL without first checking with your doctor. He or she will tell you when and how you can stop taking this medicine; stopping suddenly can make your condition worse.

If you stop your treatment suddenly, you may experience nervousness, feeling confused, hallucinations, abnormal thinking or behaviour, convulsions, uncontrollable twitching, jerking or writhing movements, fast heartbeat, high body temperature. The excessive tension (spasms) in your muscles may also become worse.

4. POSSIBLE SIDE EFFECTS

LIORESAL can have some side effects.

Not all side effects reported for LIORESAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LIORESAL, please consult your health care provider for advice.

Some effects could be serious.

If you experience any of these, **tell your doctor straight away.**

- Breathing problems.
- Feeling of confusion.
- Feeling of extreme happiness.
- Sad mood (depression).
- Loss of coordination affecting balance and walking, limb and eye movements and/or speech (signs of ataxia).
- Trembling.
- Hallucinations.
- Nightmares.
- Blurred vision/visual disturbance.
- Shortness of breath at rest or with activity, swelling in the legs and tiredness (signs of decreased cardiac output).
- Low blood pressure (hypotension).
- Skin rash.
- Difficulty passing urine, pain when passing urine or a sudden decrease in urine.
- Convulsions.
- Abdominal pain, yellowing of the skin or eyes and tiredness (signs of liver disturbance).
- Low body temperature.

- Slow heartbeat
- Symptoms after suddenly stopping taking the medicine (drug withdrawal syndrome) as explained in section above (Effects when treatment with LIORESAL is stopped)

Tell your doctor if you notice any of the following:

Other very frequent side effects:

These are likely to affect more than 10 in every 100 people

Drowsiness, sleepiness, nausea

Other frequent side effects:

These are likely to affect between 1 and 10 in every 100 people

Feeling faint, weariness, exhaustion, dizziness, headache, inability to sleep, weakness in arms and legs, pain in muscles, uncontrollable eye movement, dry mouth, disturbance of the digestive tract, retching, vomiting, constipation, diarrhoea, sweating a lot, passing more urine than normal, bedwetting.

Other less frequent side effects:

These are likely to affect between 1 and 10 in every 10'000 people

Tingling or numbness of the hands and/or feet, difficulty in speaking, taste disturbance, abdominal pain, sudden decrease in urine, inability to get or to maintain an erection (impotence).

Also reported (frequency unknown):

Increased blood sugar.

If any of these affects you severely, **tell your doctor**.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LIORESAL.

5. How to store LIORESAL

Store below 30 °C and protect from moisture.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Content of the pack and other information

What LIORESAL contains

The active substance is baclofen 10 mg or 25 mg per tablet.

The other ingredients are: silica aerogel; cellulose microcrystalline; magnesium stearate; polyvidone; wheat starch.

What LIORESAL looks like and contents of the pack

LIORESAL is supplied as uncoated tablets of 10 mg and 25 mg in packs of 30

LIORESAL 10[®]:

White to faintly yellowish, round, flat tablets with a slightly bevelled edge. One side carries the debossment "CG", the other the debossment "K", score, "J".

LIORESAL 25[®]:

White to faintly yellowish, round, flat tablets with a slightly bevelled edge with the CG inscription on one side and the UR inscription with brake scored on the other side.

Holder of the Certificate of Registration:

NOVARTIS SOUTH AFRICA (Pty) Ltd
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Waterfall City,
Jukskei View
Johannesburg,
2090

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