

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**  
The medicine is dispensed with a doctor's prescription only

## **Lioresal® 10 mg Tablets**

## **Lioresal® 25 mg Tablets**

### **Composition:**

Each tablet contains:  
baclofen 10 mg

Each tablet contains:  
baclofen 25 mg

Inactive ingredients and allergens: see section 2 "Important information about some of this medicine's ingredients" and section 6 "Further information".

**Read the leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

### **1. What is the medicine intended for?**

Lioresal is intended for muscle spasms caused by different factors.

#### **Therapeutic group:**

Antispastic with spinal site attack.

Lioresal is used to reduce and relieve excessive muscle stiffness and/or spasms due to various diseases and conditions.

Muscle relaxation by Lioresal improves the ability to move and makes it easier to perform daily activities.

If you have questions about how Lioresal works or why this medicine has been prescribed for you, refer to the doctor.

### **2. Before using the medicine**

#### **Do not use the medicine if:**

- You are sensitive (allergic) to baclofen or to any of the other ingredients of the medicine, see section 6.
- You have or have ever had a stomach ulcer.

### **Special warnings regarding use of the medicine**

#### **Before treatment with Lioresal, tell the doctor if:**

- You had a stroke.
- You have epilepsy.

- You have any mental illness.
- You are being treated for high blood pressure.
- You have Parkinson's disease.
- You suffer from liver, kidney or lung disease.
- You have diabetes.
- You have difficulties in urinating.
- You are pregnant or breastfeeding (see section "Pregnancy and breastfeeding").
- You have an intolerance to wheat starch (the tablets contain a small amount of wheat starch. They are suitable for people with celiac disease. However, if you have a wheat allergy [a different condition than celiac disease], do not take the medicine).
- You have a history of addiction to or dependence on the medicine.

If one or more of these conditions apply to you, inform the doctor or pharmacist before taking Lioresal, since Lioresal might not be suitable for you.

### **Children and adolescents**

Lioresal is not intended for children weighing less than 33 kg.

### **Drug interactions**

**If you are taking or have recently taken other medicines, including nonprescription medicines or nutritional supplements, tell the doctor or pharmacist.** In particular, inform the doctor or pharmacist if you are taking:

- Other medicines to relax muscles, e.g., tizanidine.
- Medicines to treat mood disorders such as lithium or tricyclic antidepressants such as amitriptyline.
- Medicines used to treat high blood pressure, e.g., diltiazem.
- Other medicines which also affect the kidneys, e.g., ibuprofen.
- Medicines to treat Parkinson's disease, e.g., levodopa or carbidopa.
- Medicines which slow down the nervous system, e.g., anti-histamines such as promethazine, sedatives such as temazepam, opiates for pain relief such as morphine and anti-convulsants (anti-epileptic medicines such as carbamazepine).

### **Using this medicine and food**

Take Lioresal with a meal and a little liquid.

### **Pregnancy and breastfeeding**

Consult with the doctor or pharmacist before taking any medicine.

Do not use Lioresal during pregnancy, unless the doctor advises you to do so. Inform your doctor if you are pregnant, or planning a pregnancy. If you have to take Lioresal during pregnancy, your unborn baby will also be exposed to Lioresal. After birth, your baby may have withdrawal symptoms, such as convulsions (withdrawal symptoms are described in the section "If you stop taking the medicine").

Only a small amount of Lioresal passes into breast milk. Your doctor will discuss with you whether you can breastfeed while taking Lioresal.

### **Driving and operating machinery**

Some patients may feel drowsy and/or dizzy or have vision disturbances while taking Lioresal. If this happens to you, do not drive a car or do other things that requires you to be alert (such as operating tools or machinery), until these effects have worn off.

Children should be cautioned against riding a bicycle or playing near the road, and the like.

### **Important information about some of this medicine's ingredients**

Lioresal contains wheat starch.

This medicine contains a very small amount of gluten (from wheat starch) and is very unlikely to cause problems if you have celiac disease.

If you have a wheat allergy (a different condition from celiac disease), you should not take this medicine.

One tablet of Lioresal 10 mg contains 61 mg wheat starch.

One tablet of Lioresal 25 mg contains 83 mg wheat starch.

### **Special warnings**

- Be careful when drinking alcoholic beverages - they may affect you more than usual.
- Some people being treated with baclofen have thoughts of harming or killing themselves or have tried to kill themselves. Most of these people also had depression, had been using alcohol excessively or were prone to suicidal thoughts. If you have thoughts of harming or killing yourself at any time, refer to a doctor immediately or proceed 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.
- Your doctor may want to perform periodic tests while you are taking Lioresal.
- If you are about to undergo any kind of operation, inform the doctor that you are taking Lioresal.

## **3. How should you use the medicine?**

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen.

The dosage and treatment regimen will be determined by the doctor only.

The doctor will tell you exactly how many Lioresal tablets to take. The doctor may increase or decrease the dosage of the medicine, depending on your response to the treatment.

The dosage of Lioresal depends on the patient's response to the medicine. You will start taking a low dosage of the medicine, which will be increased gradually over a few days, under the supervision of the doctor, until you reach the dosage which is right for you. The doctor will tell you when you should take the medicine.

**Do not exceed the recommended dose.**

**Method of administration**

Do not chew!

Take the medicine with a meal and swallow the tablets with a little liquid, such as a milky beverage.

If you feel sick after taking Lioresal Tablets, you may find it helps to take them with food or a milky beverage.

Lioresal 10 mg – the tablet can be halved.

Lioresal 25 mg – the score line is intended to help in breaking to ease swallowing, and not to divide into equal doses.

Taking Lioresal at the same time every day will help you remember when to take the medicine.

Use the medicine at set intervals, as determined by the attending doctor.

**If you accidentally took a higher dosage**, inform the doctor immediately.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

Signs of overdose are: ringing in the ears.

**If you forget to take the medicine**

If you forgot to take this medicine at the designated time, **do not** take a double dose, take the next dose at the usual time and consult the doctor.

Adhere to the treatment regimen as recommended by the doctor.

**If you stop taking the medicine**

Do not stop taking Lioresal suddenly. Before discontinuing, discuss with the doctor or pharmacist; if the doctor decides to stop the treatment with Lioresal, the dose will be gradually reduced to prevent withdrawal symptoms, such as muscle spasms and increased muscle rigidity, fast heart rate, fever, confusion, hallucinations, changes in mood and emotions, mental disorders, feelings of persecution or convulsions.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

**4. Side effects**

As with any medicine, use of Lioresal may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

**The side effects listed below have been reported:**

*Very common side effects (effects occurring in more than 1 user in 10):*  
tiredness; sleepiness; nausea

*Common side effects (effects occurring in up to 1 user in 10):*

Increased limb weakness or feeling tired and exhausted; muscle pain

Headache; dizziness or light-headedness

Breathing difficulties

Sleeplessness

Mood swings, confusion, hallucinations or nightmares

Dry mouth

Eye problems

Unsteadiness, trembling or other problems with muscle control

Low blood pressure (fainting)

Gastrointestinal disorders: stomach problems including retching; vomiting;

constipation; diarrhea

Increased sweating; rash

Urinating more than usual or pain upon passing urine.

*Rare side effects (effects occurring in up to 1 user in 1,000):*

Numbness or tingling of the hands or feet

Increased muscle spasm

Disturbed sense of taste

Slurred or slow speech

Stomach ache

Liver problems

Difficulty in passing urine

Sexual problems in men, e.g., impotence

Convulsions (particularly in epileptics).

*Very rare side effects (effects occurring in less than 1 user in 10,000):*

Hypothermia (low body temperature).

**Additional side effects (frequency is unknown)**

Raised, itchy rash (urticaria – also known as nettle rash or hives)

Slow heartbeat

Increase in blood sugar level

Breathing difficulties while sleeping (sleep apnea syndrome)

Withdrawal symptoms caused by stopping treatment suddenly (see section “**If you stop taking the medicine**”).

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.**

**Reporting side effects**

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

**5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

**Storage conditions:**

- Lioresal 10 mg - Store below 30°C.
- Lioresal 25 mg – Store below 25°C.

Store in the original package to protect from moisture.

If the doctor has told you to stop taking Lioresal tablets, give the remaining tablets to the pharmacist, for disposal. Only keep the tablets if the doctor has told you to do so. Do not discard the tablets into the wastewater or the waste bin. This is in order to protect the environment.

**6. Further Information**

In addition to the active ingredient, the medicine also contains:

Wheat starch PH, cellulose microcrystalline, povidone, silica colloidal anhydrous, magnesium stearate.

What the medicine looks like and the contents of the package:

- Lioresal 10 mg – white-yellowish, round and flat tablets with beveled edges. “CG” is printed on one side and “KJ” with a score line on the other side.
- Lioresal 25 mg – white-yellowish, round and flat tablets, with beveled edges. “CG” is printed on one side and “UR” with a score line on the other side. This score line is only intended for easing swallowing and not for dividing into two doses.

Lioresal 10 mg and 25 mg packages contain 50 tablets.

**Registration holder and importer’s name and address:**

Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in January 2022 according to MOH guidelines.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:**

Lioresal 10 mg: 120-93-23361

Lioresal 25 mg: 124-09-23362