

**Package Leaflet: Information
for the patient**

**Lioresal® 10 mg Tablets
(baclofen)**

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 onto 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 Lioresal is and what it is used for
2. What you need to know before you take Lioresal
3. How to take 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

Lioresal contains the active ingredient, baclofen. Baclofen is a muscle-relaxant drug.

Lioresal is used to relieve muscle rigidity (spasticity) or spasms in adults and children, which may occur as a result of illnesses such as cerebral palsy, multiple sclerosis, cerebrovascular accidents, spinal cord diseases and other nervous system disorders.

2. What you need to know before you take Lioresal

Do not take Lioresal if:

- you are allergic (hypersensitive) to baclofen or any of the other ingredients of Lioresal (listed in Section 6)

If you are not sure, talk to your doctor or pharmacist before taking Lioresal.

Warnings and precautions

Check with your doctor or pharmacist before taking your medicine if:

- you have epilepsy
- you have a mental illness such as schizophrenia, psychosis, depressive or manic disorders or confusional states
- you have high blood pressure
- you have Parkinson's disease
- you have any liver, kidney or lung disease
- you have diabetes
- you have difficulties in urinating
- you have a disturbance of the blood circulation in

your brain

- you have a history of alcoholism or you drink alcohol to excess or you have a history of drug abuse or dependence

- Some people being treated with baclofen have had 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 having thoughts of killing themselves. 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 behaviour and ask them to read this leaflet.
- If you have symptoms such as increased sleepiness, new onset of drowsiness, confusion or muscle jerks, those could be a sign of decreased brain function (encephalopathy); please contact your doctor immediately.

- you have a disease of your blood pigment called "Porphyria"
- you have ever had an ulcer in your stomach or gut
- your child is under the age of one year
- you are pregnant and taking Lioresal during pregnancy, your newborn may have convulsions and other symptoms related to sudden stop of treatment just after delivery . Your doctor may need to give your newborn small doses of Lioresal and gradually reduce the dose to control and prevent the symptoms. This recommendation for newborns is based on a limited number of case reports in the literature.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Lioresal.

Children and adolescents

Lioresal tablets are not suitable for use in children with a body weight below 33 kg.

Other medicines and Lioresal

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

This is because Lioresal can affect the way some other medicines work. Also some other medicines can affect the way Lioresal works.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- antidepressants e.g. tricyclic antidepressants and monoamine oxidase inhibitors
- medicines that lower blood pressure including medicines used to treat high blood pressure
- other drugs which affect the kidney e.g. ibuprofen
- medicines used to treat Parkinson's disease
- medicines which slow down the nervous system e.g. anti-histamines, opiate pain killers, sedatives and anti-convulsants (some of these can be bought over the counter)
- medicines for diabetes such as insulin – your doctor may need to increase your dose
- lithium – for mood problems.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking

Lioresal.

Operations and tests

- Your doctor may want to give you a check up from time to time while you are being treated with Lioresal, especially if you have diabetes or any liver problems.
- If you are going to have an operation of any kind, make sure that your doctor knows you are being treated with Lioresal.

Lioresal with food and alcohol

- You should not drink alcohol during your treatment with Lioresal – it may affect you more than usual.

Older people (aged 65 years or above) or people with muscle spasms caused by a brain disease

If you are in one of these groups, you may experience more side effects. Therefore, your doctor will keep you under appropriate surveillance and may adapt the dose of Lioresal you take.

Pregnancy and breast-feeding and fertility

Talk to your doctor before taking this medicine if you are pregnant or might become pregnant. You should not use Lioresal during pregnancy unless your doctor advises you to do so. If you have to take Lioresal during pregnancy, your baby may have convulsions and other symptoms related to sudden stop of treatment just after delivery. Talk to your doctor before taking this medicine if you are breast-feeding. Lioresal passes into mother's milk but in small amounts and no effects on your baby are expected.

Driving and using machines

Some people may feel drowsy or dizzy or have problems with their eyes while they are being treated with Lioresal. If this happens, you should not drive or do anything that requires you to be alert (such as operate tools or machinery) until these effects have worn off.

Lioresal contains wheat starch. This medicine contains only very low levels of gluten (from wheat starch). It is regarded as 'gluten-free'* and is very unlikely to cause problems if you have coeliac disease.

One tablet of Lioresal 10 mg contains no more than 6.1 micrograms of gluten.

If you have wheat allergy (different from coeliac disease) you should not take this medicine.

3. How to take Lioresal

The doctor will tell you how many Lioresal tablets to take and when to take them. Always follow the doctor's instructions carefully. The dose will be on the pharmacist's label. Check the label carefully. It is important to take your medicine at the right times. Taking Lioresal at the same time each day will help you remember when to take your medicine. Take Lioresal with meals and with a little liquid. If you feel sick after taking Lioresal, you may find it helps to take it with food or a milkdrink.

How much to take:

Adults: The usual starting dose for adults is 15 mg a day, preferably taken in 3 divided doses. The dose is then gradually increased until the best results are obtained, this may be between 30 mg to 80 mg a day, taken in 2 to 4 divided doses.

Your doctor may even decide to give you a higher dose. The maximum dose of oral solution should not exceed 100 mg (equivalent to 100 mL) a day.

Children (up to 18 years): The dose for a child is based on their body weight. The usual starting dose is 0.3 mg for each kilogram of body weight a day, in 2 to 4 divided doses (preferably in 4 doses). The daily dose is then gradually increased until it becomes sufficient for the child's individual requirements. This may be between 0.75 mg and 2 mg for each kilogram of body weight.

Lioresal tablets are not suitable for use in children with a body weight below 33 kg. If you have been treated for 6 weeks and you feel no improvement, tell your doctor. Your doctor will decide if you should continue taking Lioresal. If you have questions about how long to take Lioresal, talk to your doctor or pharmacist.

People with kidney problems

If you have kidney disease, a lower dose of 5 mg a day is used. If you are not sure how much medicine to take, ask your doctor or pharmacist.

If you take more Lioresal than you should If you accidentally take too many Lioresal tablets, tell your doctor at once or contact your nearest hospital casualty department. Take your medicines pack with you so that people can see what you have taken.

Signs of overdose are:

- unusual muscle weakness (too little muscle tone) or sudden contraction of your muscles
- drowsiness
- excessive salivation
- feeling sick (nausea), being sick (vomiting) or diarrhea difficulty in breathing
- fits (convulsions)
- loss of consciousness
- abnormally low body temperature
- feeling confused or agitated
- hallucinations
- blurred vision
- poor or absent reflexes
- high or low blood pressure
- slow, fast or irregular heart beat
- trouble breathing during sleep (sleep apnoea)
- pain in muscles, fever and dark urine (rhabdomyolysis)
- ringing in the ears
- decrease in brain function (encephalopathy)

If you have **kidney disease** and have accidentally taken more tablets or more oral solution than **your doctor** has prescribed, you may experience neurological symptoms of overdose (e.g. drowsiness, feeling confused, hallucinations).

If you forget to take Lioresal

If you forget a dose, just take your next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Lioresal

You should not stop treatment suddenly. If the doctor decides to stop your treatment, the dose will be reduced gradually to prevent withdrawal symptoms such as muscle spasms and increased muscle rigidity, too much muscle tone, fast heart beat, high body temperature, pain in muscles, fever and dark urine fever, confusion, seeing things that are not really there (hallucinations), changes in mood and emotion, mental disorders, feeling persecuted or convulsion (fits).

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

4. Possible side effects

Lioresal is suitable for most people, but like all medicines, it can sometimes cause side effects. They are often mild and usually occur at the start of treatment; they normally wear off after a few days.

Some side effects can be serious

Stop taking Lioresal and tell your doctor straight away if you notice the following symptoms:

- breathing difficulties
 - shortness of breath at rest or with activity, swelling in the legs and tiredness (signs of decreased cardiac output)
 - feeling confused, extremely happy or depressed
 - loss of coordination affecting balance and walking, limb and eye movements or speech (signs of ataxia)
 - trembling
 - nightmares or hallucinations
 - problems with eyesight
 - low blood pressure (fainting)
 - skin rash and hives
 - urinary incontinence, problems when urinating or a sudden decrease in urine
 - seizures
 - abdominal pain, yellowing of the skin or eyes and tiredness (signs of liver problems).
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- slow heart beat
 - symptoms following sudden discontinuation of the medicine (drug withdrawal syndrome) as explained above in Section 3 (if you stop taking Lioresal)
- If you experience any of the above, stop taking Lioresal and tell your doctor straight away.

The side effects listed below have also been reported:

Very common (more than 1 in 10 people have experienced):

- feeling tired, drowsy or sick.

Common (up to 1 in 10 people have experienced):

- tiredness
- headache, dizziness or light-headedness
- insomnia
- being sick, retching, constipation or diarrhoea
- dry mouth
- weakness or pain in your muscles
- excessive sweating.

Rare (up to 1 in 1000 people have experienced)

- slurred speech
- a change in the way things taste
- tingling hands or feet
- sexual problems in men e.g impotence

Very Rare (up to 1 in 10,000 people have experienced)

- hypothermia

Also reported (frequency unknown)

- increased blood sugar
- Trouble breathing during sleep (sleep apnoea syndrome)
- Swelling of the ankles, feet or lower legs
- Swelling face
- Allergic reaction (hypersensitivity)

- Hair loss
- Sexual difficulties
- Decreased brain function (encephalopathy)
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If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 HPRA

Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lioresal

- Keep this medicine out of the sight and reach of children. Do not use after the expiry date which is stated on the label and carton after exp MM/YYYY. The expiry date refers to the last day of that month.
- Store your medicine in the original package and keep the bottle tightly closed in order to protect from moisture.
- Store below 25°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 protect the environment.

6. Contents of the pack and other information

What Lioresal contains

- The active substance is baclofen. Each tablet contains 10 mg of baclofen.
- The other ingredients are silica colloidal anhydrous, microcrystalline cellulose, magnesium stearate, povidone and wheat starch.

What Lioresal looks like and the contents of the pack

Lioresal tablets are 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".

Pack sizes: Lioresal 10 mg tablets are packed in Blister packs made of PVC/PE/PVDC backed with a heat sealable lacquered aluminium foil and blister packs made of PVC backed with a heat sealable lacquered aluminium foil.

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