



Package Leaflet : Information for the patient

Lioresal® 5 mg/5 ml
Oral Solution
(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..

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

Take special care

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.

- 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:

- Other medicines to relax muscles e.g. tizanidine
- 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 sodium.

This medicine contains 48.6 mg sodium (main component of cooking/table salt) in each dose (30 ml) of Lioresal Oral Solution. This is equivalent to 2.4% of the recommended maximum daily dietary intake of sodium for an adult.

Lioresal contains 385 mg sorbitol in each ml of syrup.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Lioresal contains methyl hydroxybenzoate and propyl parahydroxybenzoate, these may cause allergic reactions (possibly delayed)

Lioresal contains 0.01 mg benzyl alcohol in each ml.

Benzyl alcohol may cause allergic reactions.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children.

Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor.

Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Ask your doctor or pharmacist for advice if you have a liver or kidney disease or if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

3. How to take Lioresal

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure

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 milk drink. Shake the bottle well.

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.

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 much Lioresal, tell your doctor at once or contact your nearest hospital casualty department. Take your medicine 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 diarrhoea
- 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

If you have **kidney disease** and have accidentally taken more tablets or more syrup 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 convulsions (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
- Difficulty passing urine, pain when passing urine or a sudden decrease in urine.
- seizures
- abdominal pain, yellowing of the skin or eyes and tiredness (signs of liver problems).
- slow heart beat
- symptoms following sudden discontinuation of the medicine (drug withdrawal syndrome) as explained above in section “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):

- tiredness

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

- feeling lethargic (having no energy)
- 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
- Raised, itchy rash (urticaria – also known as nettle rash or hives).
- Slow heart beat.
- Trouble breathing during sleep (sleep apnoea syndrome)
- Swelling of the ankles, feet or lower legs
- Swelling face
- Allergic reaction (hypersensitivity)
- Hair loss
- Sexual difficulties

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 glass bottle in order to protect from light.
- Store below 25°C. Do not refrigerate.
- After dilution, the product may be stored at room temperature for up to 14 days.
- 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 Lioresal contains

- The active substance is baclofen. Each 1 ml of Lioresal oral solution contains 1mg of baclofen.
- The other ingredients are liquid sorbitol

(non-crystallising), methylhydroxybenzoate (E216) and propyl hydroxybenzoate (E218), carmellose sodium, water, raspberry flavour which contains flavouring substances identical to natural substances, natural flavouring substances, glyceryl triacetate (E1518) benzyl alcohol and water.

What Lioresal looks like and the contents of the pack

Lioresal liquid is a clear, slightly yellow, raspberry-flavoured oral solution. The liquid comes in 300 ml bottles with child-proof closures.

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