

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

Patient Information Leaflet

What you need to know about Lioresal Tablets

Your doctor has decided that you or your child needs this medicine to help treat your condition.

Please read this leaflet carefully before you start to take your medicine. It contains important information. Keep the leaflet in a safe place because you may want to read it again.

If you have any other questions, or if there is something you don't understand, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be 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.

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1. What Lioresal Tablets are and what they are used for

Lioresal Tablets contain 10 mg of the active ingredient baclofen.

Baclofen is a muscle-relaxant drug. Lioresal Tablets are used to reduce and relieve the excessive tension in your muscles (spasms) occurring in various illnesses such as cerebral palsy, multiple sclerosis, cerebrovascular accidents, spinal cord diseases and other nervous system disorders.

2. Things to consider before you start to take Lioresal Tablets

Some people MUST NOT take Lioresal Tablets. Talk to your doctor if:

- you think you may be allergic to baclofen or to any of the other ingredients of the tablets, (these are listed at the end of the leaflet.)
- you have ever had a stomach ulcer.

You should also ask yourself these questions before taking Lioresal Tablets:

- Have you had a stroke?
- Do you have epilepsy?
- Do you suffer from any mental illness?
- Are you being treated for high blood pressure?
- Do you have Parkinson's disease?
- Do you suffer from any liver, kidney or lung disease?
- Do you have diabetes?
- Do you have difficulties in urinating?

- Are you pregnant or breast-feeding? (See section “Pregnancy and breast-feeding”).
- Do you have an intolerance to wheat flour? (The tablets contain small amounts of wheat starch. They are suitable for people with coeliac disease, however if you have a wheat allergy (different from coeliac disease), you should not take this medicine.)
- Do you have a history of drug abuse or dependence

If the answer to any of these questions is YES, tell your doctor or pharmacist because Lioresal Tablets might not be the right medicine for you.

Are you taking other medicines?

Some medicines can interfere with your treatment. Tell your doctor or pharmacist if you are taking any of the following:

- Other medicines to relax muscles e.g. tizanidine
- Medicines to treat mood disorders such as lithium or tricyclic antidepressants such as amitriptyline
- Medicines that lower blood pressure including medicines used to treat high blood pressure e.g. diltiazem
- Other drugs which also affect the kidney, e.g. ibuprofen
- Medicines for 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).

Always tell your doctor or pharmacist about all the medicines you are taking. *This means medicines you have bought yourself as well as medicines on prescription from your doctor.*

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

You should not use Lioresal during pregnancy unless your doctor advises you to do so. Tell your doctor if you are pregnant, or planning to become pregnant.

If you have to take Lioresal during pregnancy, your unborn baby will also be exposed to Lioresal. After birth your baby may develop withdrawal symptoms such as convulsions (symptoms of withdrawal are described in the section “**If you stop taking Lioresal**”).

Only a very small amount of Lioresal passes into breast milk. Your doctor will discuss with you whether you should breast-feed whilst taking Lioresal.

Will there be any problems with driving or using machinery?

Some people may feel drowsy and/or dizzy or have problems with their eyes while they are taking Lioresal Tablets. 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.

Other special warnings

- Be careful when drinking alcohol - it may affect you more than usual
- 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.

- Your doctor may want to give you a check up from time to time while you are taking Lioresal Tablets.
- If you are going to have an operation of any kind, make sure that the doctor knows that you are taking Lioresal Tablets.

Children and adolescents:

Lioresal Tablets are not suitable for use in children under 33 kg body weight.

Lioresal Tablet contains Wheat starch :

This medicine contains only very low levels of gluten (from wheat starch) 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 Tablets

The doctor will tell you how many Lioresal Tablets to take and when to take them. Always follow his/her instructions carefully. The dose will be on the pharmacist's label. Check the label carefully. If you are not sure, ask your doctor or pharmacist.

The doctor will tell you the best time to take the medicine. Some people take it only at night or before doing a task such as washing, dressing, shaving, etc.

The final dose of Lioresal depends on how each person responds to the drug. You will be started on a low dose, and this will be increased gradually over a few days, under the supervision of the doctor, until you are having the dose which is right for you. If the starting dose is too high, or if the dose is increased too quickly, you may experience side effects, particularly if you are elderly, have kidney problems or have had a stroke.

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

Adults

- The usual dose is 20 mg (2 tablets) three times a day.
- The maximum daily dose is 100 mg (10 tablets) except if you are in hospital when a higher dose may be used.

Children (0 to < 18 years)

Children's treatment is adjusted to their body weight. Children's treatment usually starts with a very low dose (approximately 0.3 mg/kg/day), in 2-4 divided doses (preferably in 4 doses). The dosage is then gradually increased until it becomes sufficient for the child's individual requirements, this may be between 0.75 and 2 mg/kg body weight. The total daily dose should not exceed a maximum of 40 mg/day in children below 8 years of age. In children over 8 years of age a maximum daily dose of 60 mg/day may be given. Lioresal Tablets are not suitable for use in children below 33 kg body weight.

Patients with kidney problems

You will probably be given a much lower dose. The doctor will decide what the dose should be.

What if you forget to take a dose?

If you forget to take a dose, take the next dose at the usual time. DO NOT take a double dose.

What if you take too much?

If you accidentally take too many Lioresal Tablets, tell your doctor at once or contact your nearest hospital casualty department. Take your medicine with you.

Signs of overdose are : Ringing in the ears.

If you stop taking Lioresal

You should not stop taking Lioresal Tablets suddenly. If the doctor decides to stop your treatment with Lioresal Tablets, the dose will be reduced gradually to prevent withdrawal symptoms such as muscle spasms and increased muscle rigidity, too much muscle tone, fast heart rate, fever, confusion, hallucinations, changes in mood and emotion, mental disorders, feeling persecuted or convulsions (fits).

4. Possible side effects

Lioresal Tablets are suitable for most people, but, like all medicines, they can sometimes cause side effects.

The side effects listed below have been reported:

More than 1 in 10 people have experienced:

Tiredness, sleepiness, nausea (feeling sick).

Up to 1 in 10 people have experienced:

Excessively weak limbs or feeling tired and exhausted, aching muscles
Headache, dizziness or light-headedness
Breathing difficulties
Sleeplessness
Mood changes, confusion, hallucinations or nightmares
Dry mouth
Problems with their eyes
Unsteadiness, trembling or other problems with muscle control
Low blood pressure (fainting)
Stomach problems including retching, vomiting, constipation and diarrhoea
Excessive sweating, rash
Increased need to pass urine or pain on passing urine.

Up to 1 in 1,000 people have experienced:

Numbness or tingling in 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 rarely (less than 1 in 10,000) people have experienced:

Hypothermia (low body temperature).

Other side-effects (how often they happen is not known)

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

Slow heart beat.

Increase in 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

Symptoms caused by stopping treatment suddenly (see ‘3. How to take Lioresal Tablets’).

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to adjust the dose or give you a different medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lioresal Tablets

Keep this medicine out of the sight and reach of children.

Store below 25°C. Store in the original package in order to protect from moisture.

Do not take the tablets after the expiry date which is printed on the outside of the pack.

If your doctor tells you to stop taking Lioresal Tablets, please take any which are left back to your pharmacist to be destroyed. Only keep them if the doctor tells you to. Do not throw them away with your normal household water or waste. This will help to protect the environment.

6. Further information

Lioresal Tablets are white to faintly yellowish, round, flat tablets measuring about 7mm in diameter and about 3mm in thickness with a slightly bevelled edge. One side carries the **debossement** “CG”, the other the **debossement** “K”, **score**, “J”. They contain 10 mg of the active ingredient, baclofen and also inactive ingredients silica, microcrystalline cellulose, magnesium stearate, povidone and wheat starch.

The tablets come in PVC blister packs of 84, 100 and 200 and containers of 84 and 200. Some of the pack sizes may not be marketed.

Marketing Authorisation Holder and Manufacturer

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If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at Novartis Pharmaceuticals UK Ltd, telephone number 01276 698370.