

LIORESAL[®] Liquid (baclofen)

Patient Information Leaflet

What you need to know about Lioresal Liquid

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.

In this leaflet:

1. What Lioresal Liquid is and what it's used for
2. Things to consider before you start to take Lioresal Liquid
3. How to take Lioresal Liquid
4. Possible side effects
5. How to store Lioresal Liquid
6. Further information

1. What Lioresal Liquid is and what it's used for

Lioresal Liquid is a syrup containing 5 mg of the active ingredient, baclofen, in each 5 ml.

Baclofen is a muscle-relaxant drug. Lioresal Liquid is 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 Liquid

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

- you think you may be allergic to baclofen or to any of the other ingredients of the liquid, (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 Liquid:

- 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 some sugars? (The liquid contains sorbitol.)
- 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 Liquid 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 Liquid. 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 Liquid.
 - If you are going to have an operation of any kind, make sure that the doctor knows that you are taking Lioresal Liquid.
 - There have been reports of reduction in brain function (encephalopathy) in some patients taking Lioresal at prescribed doses, which resolved after stopping the medication. Symptoms include increased sleepiness, new onset of drowsiness, confusion, muscle jerks or coma. If you experience any of these symptoms, seek medical attention immediately. Your physician will decide whether baclofen has to be discontinued.

Lioresal Liquid contains Sodium, Sorbitol, Benzyl Alcohol, Methyl para-hydroxybenzoate (E218) and Propyl para-hydroxybenzoate (E 216).

- **Sodium** - This medicine contains less than 1 mmol sodium (23mg) per 5ml, that is to say essentially 'sodium free'. When the dose is greater than 14ml it cannot be considered 'sodium free' and it should be taken into consideration by patients on a controlled sodium diet. At maximum daily dose (120ml) this medicine contains 194.4mg of sodium. This is equivalent to 9.72% of the recommended maximum daily dietary intake of sodium for an adult.
- **Sorbitol** - This medicine contains 1925mg sorbitol in each 5ml 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.
- **Benzyl alcohol** - this medicine contains 0.06mg benzyl alcohol in each 5ml. Benzyl alcohol may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gaspings 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").
- **Methyl para-hydroxybenzoate (E 218) and Propyl para-hydroxybenzoate (E 216)** may cause allergic reactions (possibly delayed)

3. How to take Lioresal Liquid

The doctor will tell you how much Lioresal Liquid to take and when to take it. 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 Liquid, you may find it helps to take it with food or a milk drink.

Adults

- The usual dose is 20 mg (20 ml) three times a day.
- The maximum daily dose of oral syrup should not exceed 100 mg (equivalent to 100 mL) a day.

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 maximum daily dose should not exceed 2 mg/kg/day. The maximum daily dose should not exceed 40 mg/day in children below 8 years old and 60 mg/day in children 8 years and older.

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 much Lioresal Liquid, 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 and decrease in brain function (encephalopathy).

If you stop taking Lioresal

You should not stop taking Lioresal Liquid suddenly. If the doctor decides to stop your treatment with Lioresal Liquid, 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 Liquid is suitable for most people, but, like all medicines, it 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 heartbeat.
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 Liquid').
Reduction in brain function (encephalopathy)

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 Liquid

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 light. Do not refrigerate.

Any syrup which has been diluted with water can be stored at room temperature for up to 14 days.

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

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

6. Further information

Lioresal Liquid is clear, slightly yellow syrup with a raspberry flavour containing 5 mg of the active ingredient, baclofen, in each 5 ml. The liquid also contains the inactive ingredients sorbitol, methyl and propyl hydroxybenzoate, carmellose sodium, Raspberry flavour (contains benzyl alcohol) and water.

The liquid comes in 300 ml bottles with child-proof closures.

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.