

PART III: CONSUMER INFORMATION**PrLIORESAL®
Baclofen Tablets**

This leaflet is part III of a three-part "Product Monograph" published when LIORESAL® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about LIORESAL®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

LIORESAL is used to reduce and relieve the excessive stiffness and/or spasms in your muscles occurring in various conditions such as multiple sclerosis and diseases or injuries of the spinal cord.

What it does:

Due to the relaxation of muscle and the consequent relief from pain, LIORESAL improves your ability to move, makes it easier for you to manage your daily activities and facilitates physiotherapy.

If you have any questions about how LIORESAL works or why this medicine has been prescribed for you, ask your doctor.

When it should not be used:

Do not take LIORESAL:

- If you are allergic (hypersensitive) to baclofen or any of the other ingredients listed in "What the nonmedicinal ingredients are".

If this applies to you, tell your doctor without taking LIORESAL.

If you think you may be allergic, ask your doctor for advice.

What the medicinal ingredient is:

The active substance of LIORESAL is baclofen.

What the non-medicinal ingredients are:

The non-medicinal ingredients are: microcrystalline cellulose, cornstarch, magnesium stearate and povidone.

What dosage forms it comes in:

LIORESAL is available in 10 mg and 20 mg tablets.

WARNINGS AND PRECAUTIONS

BEFORE you use LIORESAL talk to your doctor or pharmacist if

you:

- Have kidney disease. Your doctor will decide whether or not LIORESAL is the appropriate treatment for you;
- Are suffering from epilepsy (seizures);
- Have acute pain in your stomach (ulcer) or intestines, breathing problems, liver disease, or a disturbance of blood circulation in your brain;
- Are taking medicines for arthritis or pain (see section: "Interactions with this medication");
- Have difficulty urinating;
- Have Parkinson's disease or certain mental illnesses accompanied by confusion or depression;
- Are diabetic.

Older people (aged 65 years or above) or people with a disturbance of circulation in the brain

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.

Children and adolescents

Safe use of LIORESAL in children under age 12 has not been established and it is therefore not recommended for use in children.

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, planning to become pregnant, or breast-feeding. He or she will discuss with you the potential risk of taking LIORESAL during pregnancy or if you are breast-feeding. Use of LIORESAL during pregnancy may result in the newborn experiencing withdrawal from the drug including, irritability, high-pitched crying, trembling, increased muscle tone, excessive sucking, disordered sleep, increase in body temperature, uneven discolored patches on the skin, and convulsions and other symptoms related to sudden stop of treatment sometime after delivery. Your doctor may need to treat your newborn for withdrawal reactions.

Driving and using machines

In some people, LIORESAL may be associated with dizziness, sleepiness or visual disturbance. If this happens to you, do not drive a car, use a machine, or do other things that need your full attention.

Further safety measures

Before having any kind of surgery (including by the dentist), or emergency treatment, tell the doctor in charge that you are taking LIORESAL.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with LIORESAL include:

- Alcohol;
- Sedative drugs;
- Medicines used to treat mood disorders such as antidepressants and lithium;
- Medicines used to treat high blood pressure;
- Medicines used to treat Parkinson's disease;
- Medicines for arthritis or pain.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You should not drink alcohol during your treatment with LIORESAL.

PROPER USE OF THIS MEDICATION

Usual dose:

Follow your doctor's instructions carefully. Do not exceed the recommended dose.

How much LIORESAL to take

Treatment usually starts with 15 mg daily, preferably taken in divided doses. The dose is then gradually increased until the best results are obtained; this may be between 40 mg to 80 mg per day, taken in divided doses.

The dose prescribed by your doctor may be different from that written here. If this is the case, follow the doctor's instructions.

Your doctor will tell you exactly how many tablets of LIORESAL to take.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

When to take LIORESAL

Taking LIORESAL at the same time each day will help you to remember when to take your medicine.

How to take LIORESAL

Be sure to take this medicine regularly, and exactly as your doctor tells you. This will help you to get the best results and reduce the risk of side effects.

How long to take LIORESAL

Continue taking LIORESAL as your doctor tells you.

If you have questions about how long to take LIORESAL, talk to your doctor or your pharmacist.

Do not suddenly stop taking LIORESAL without first checking with your doctor. He or she will tell you when and how you can stop taking this medicine; stopping suddenly can make your condition worse.

If you stop your treatment suddenly, you may experience: nervousness, feeling confused, hallucinations, abnormal thinking or behaviour, convulsions, uncontrollable twitching, jerking or writhing movements, fast heart beat, high body temperature. The excessive stiffness (spasms) in your muscles may also worsen.

Overdose:

If you have accidentally taken many more tablets than your doctor has prescribed, seek immediate emergency medical treatment, even though you do not feel sick.

The main symptoms of overdose are drowsiness, breathing difficulties, trouble of consciousness and being unconscious (coma).

Other symptoms may include: feeling confused, hallucinations, agitation, convulsions, blurred vision, unusual muscle weakness, sudden contraction of the muscles, poor or absent reflexes, high or low blood pressure, slow, fast or irregular heart beat, low body temperature, nausea, vomiting, diarrhea or excessive salivation, trouble breathing during sleep (sleep apnoea), pain in muscles, fever and dark urine (rhabdomyolysis).

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).

Missed Dose:

If you have forgotten to take one of your scheduled doses, take it as soon as you remember. However, if it is almost time for your next dose, do not take the missed one at the same time as the scheduled one, otherwise you will be doubling the dose. Just go back to your regular dosing timetable. If you have forgotten to take several doses you should contact your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, LIORESAL can have some side effects, although not everybody gets them. These are often mild and are usually at the start of treatment; they normally wear off after a few days.

Very common side effects

These side effects may affect more than 1 in 10 patients:

- Drowsiness, sleepiness;
- Nausea.

If any of these affects you severely, **tell your doctor.**

Common side effects

These side effects may affect between 1 and 10 in every 100 patients:

- Feeling faint, tiredness, dizziness, headache, inability to sleep, weakness in arms and legs, pain in muscles, uncontrollable eye movements, dry mouth;
- Disturbance of the digestive tract, retching, vomiting, constipation, diarrhea;
- Sweating a lot;
- Passing more urine than normal, bedwetting.

If any of these affects you severely, **tell your doctor.**

Rare side effects

These side effects may affect between 1 and 10 in every 10,000 patients:

- Tingling or numbness of the hands and/or feet, difficulty in speaking, taste disturbance;
- Abdominal pain;
- Sudden decrease in urine;
- Inability to get or to maintain an erection (impotence).

Side effect also reported (frequency unknown)

- Increased blood sugar

If any of these affects you severely, **tell your doctor.**

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical treatment
		Only if severe	In all cases	
Common	Breathing problems		√	
	Feeling of confusion		√	
	Feeling of extreme happiness		√	
	Sad mood (depression)		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical treatment
		Only if severe	In all cases	
	Loss of coordination affecting balance and walking, limb and eye movements and/or speech (signs of ataxia)		√	
	Trembling		√	
	Hallucinations		√	
	Nightmares		√	
	Blurred vision/visual disturbance		√	
	Shortness of breath at rest or with activity, swelling in the legs and tiredness (signs of decreased cardiac output)		√	
	Low blood pressure (hypotension)		√	
	Skin rash and hives		√	
	Difficulty passing urine, pain when passing urine or a sudden decrease in urine		√	
Rare	Abdominal pain, yellowing of the skin or eyes and tiredness (signs of liver disturbance)			√
	Convulsions			√
Very rare	Low body temperature		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical treatment
		Only if severe	In all cases	
Not known	Symptoms following sudden discontinuation of the medicine (drug withdrawal syndrome)		√	
	Slow heart beat		√	

This is not a complete list of side effects. For any unexpected effects while taking LIORESAL, contact your doctor or pharmacist.

MORE INFORMATION

Please consult your doctor or pharmacist with any questions or concerns you may have regarding your individual condition.

This document plus the full product monograph, prepared for health professionals can be found at:

www.novartis.ca

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at:

1-800-363-8883

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LIORESAL is a registered trademark.

HOW TO STORE IT

- Do not use after the expiry date shown on the bottle.
- Protect from heat and humidity.
- Keep out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

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- Report online at www.healthcanada.gc.ca/medeffect
 - Call toll-free at 1-866-234-2345
 - Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.