

PART III: CONSUMER INFORMATION

**PrLIORESAL® Intrathecal
(baclofen injection)
0.05 mg/mL, 0.5 mg/mL and 2 mg/mL
For intrathecal injection and infusion only**

This leaflet is part III of a three-part "Product Monograph" published when LIORESAL® IT 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® IT. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

LIORESAL Intrathecal belongs to a group of medicines called muscle relaxants. It is used to reduce and relieve the excessive stiffness and/or spasms occurring in various illnesses such as, for example, multiple sclerosis, diseases or injuries of the spinal cord, and certain brain disorders.

What it does:

The solution is injected or infused into the fluid space around the spinal cord by use of a special pump which is implanted under the skin of your abdomen. From the pump a constant amount of the solution is delivered into the fluid space around the spinal cord through a tiny tube.

Due to the beneficial effect on muscle contractions and the consequent relief from pain, LIORESAL Intrathecal improves your mobility and your ability to manage your daily activities without aid. LIORESAL also helps you to benefit more from physiotherapy.

When it should not be used:

You should not be treated with LIORESAL IT if you:

- are allergic (hypersensitivity) to LIORESAL Intrathecal or any of the other ingredients of LIORESAL Intrathecal listed below.

What the medicinal ingredient is:
baclofen.

What the nonmedicinal ingredients are:

LIORESAL IT contains: sodium chloride and water for injection

What dosage forms it comes in:

LIORESAL Intrathecal (baclofen injection) 0.05 mg/mL: Each 1 mL ampoule contains 0.05 mg baclofen for intrathecal administration.

LIORESAL Intrathecal (baclofen injection) 0.5 mg/mL: Each 20 mL ampoule contains 10 mg baclofen for intrathecal administration.

LIORESAL Intrathecal (baclofen injection) 2 mg/mL: Each 5 mL ampoule contains 10 mg baclofen for intrathecal administration.

WARNINGS AND PRECAUTIONS

LIORESAL Intrathecal is suitable for many, but not all, patients with muscle spasms.

BEFORE you use LIORESAL IT talk to your doctor or pharmacist if you:

- have any kind of infection
- have Parkinson's disease or certain mental illnesses accompanied by confusion
- have epilepsy (seizures)
- have diabetes
- ever had heart problems
- ever had kidney problems
- have breathing problems
- have acute pain in your stomach or intestine
- have abnormal blood circulation in your brain
- have ever experienced sudden episodes of high blood pressure, anxiety, excessive sweating, "goose flesh", a pounding headache, and an unusually slow heartbeat due to an overreaction of your nervous system to stimuli such as distension of the bladder and intestine, skin irritation and pain

If any of these apply to you, your doctor may not want to give you this medicine or may want to take special precautions. If you have not told your doctor about any of these things, tell him/her before you start LIORESAL Intrathecal treatment.

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

IMPORTANT: PLEASE READ

Get urgent medical help if you observe that your implanted device is not working and you also notice withdrawal symptoms (see Missed dose).

Tell your doctor immediately if you get any of these symptoms during treatment with LIORESAL Intrathecal:

- **If you have pain** in your back, shoulders, neck and buttock during the treatment (a type of spinal deformity called scoliosis)

Driving and using machines: LIORESAL Intrathecal may make you feel sleepy or dizzy. Be careful when driving a car or using a machine or doing things that need careful attention until you are feeling normal again.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including herbal and non- prescription medicines (over the counter). Some other medicines may interact with LIORESALIT. Your doctor may change the dosage or sometimes stop one of the medicines. This is particularly important for the following medicines:

- other medicines for your spastic condition
- medicines for Parkinson' disease
- medicines for epilepsy
- medicines used to treat mood disorders such as antidepressants and lithium
- medicines for high blood pressure
- other drugs which affect the kidney, e.g. ibuprofen
- opiates for pain relief
- medicines used to help you sleep or calm you down
- medicines which slow down the central nervous system, e.g. anti-histamines and sedatives (some of these can be bought over the counter)

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

Be careful if you drink alcoholic beverages during treatment with LIORESAL Intrathecal as you may feel more sleepy or dizzy than usual.

PROPER USE OF THIS MEDICATION

Usual dose:

LIORESAL Intrathecal can only be given by experienced doctors using special medical equipment. You will need to stay in hospital, at least at the beginning of treatment.

Your doctor will inject a small amount of LIORESAL Intrathecal into your spinal cord to see if it improves your muscle spasms. If it does, then a special pump will be implanted under your skin. The pump will give you a small amount of medicine all the time.

It may take several days to find out the amount of medicine that suits you best, your doctor will keep a close watch on you during this time.

After that, your doctor will still want to see you regularly to check your progress and make sure your pump is working well.

IT IS OF UTMOST IMPORTANCE THAT APPOINTMENTS TO REFILL THE PUMP ARE KEPT, OTHERWISE SPASMS MAY RECUR BECAUSE YOU ARE NOT GETTING A HIGH ENOUGH DOSE OF LIORESAL INTRATHECAL. MUSCLE SPASTICITY MAY NOT IMPROVE OR MAY WORSEN AS A RESULT.

If muscle spasticity is not improving or if you start having spasms again, either gradually or suddenly, contact your doctor immediately.

Please consult the pump manufacturer's literature for information regarding proper home care of the pump and the insertion site.

Monitoring during treatment with LIORESAL Intrathecal

You will be monitored closely in a fully equipped and staffed environment during the screening phase and dose-titration period immediately following pump implant. You will regularly be assessed for your dosage requirements, for possible side effects or evidence of infection. The functioning of the delivery system will also be checked.

Pregnancy and breast-feeding

You should tell your doctor if you are pregnant, or planning to become pregnant as LIORESAL Intrathecal should not be used during pregnancy, or if

IMPORTANT: PLEASE READ

you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Your doctor will discuss with you the potential risk of taking LIORESAL Intrathecal during pregnancy. Use of LIORESAL Intrathecal 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. The doctor will decide if you may receive LIORESAL Intrathecal in these special situations. Only very small quantities of LIORESAL pass into the breast milk. Ask your doctor if you want to breast-feed.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Signs of overdose may appear suddenly or insidiously e.g. by a malfunctioning of the pump. It is very important that you and those caring for you recognize signs of overdosage. If you experience any one or a combination of the following symptoms, tell your doctor without delay as the amount of drug you receive may be too high:

- unusual muscular weakness (too little muscle tone)
- sleepiness
- lightheadedness or dizziness
- excessive salivation
- nausea or vomiting
- difficulties in breathing, seizures or loss of consciousness
- abnormal low body temperature

Missed Dose:

Abruptly stopping LIORESAL Intrathecal can result in serious medical problems and in rare cases has been fatal.

Signs that your pump is not functioning properly or that it is not delivering the right amount of medication include an increase or return in spasticity, itching, low blood pressure, lightheadedness, tingling

sensation, high fever, altered mental status, muscle rigidity or new muscle weakness or paralysis, persistent erection of the penis (priapism) and infection (sepsis). It is important to tell your doctor immediately if you experience any of the above symptoms. These signs may be followed by more serious side effects (including death) unless you are treated immediately.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, patients treated with LIORESAL Intrathecal, may experience some side effects, although not everybody gets them. These occur more often at the start of treatment during your hospital stay but they may also occur later and should be checked with your doctor.

Very common: Drowsiness, muscle weakness

Common: Feeling of anxiety, sedation and weariness (exhaustion), weakness in the legs, stiffness in the muscles, dizziness/light-headedness, headache, sleepiness, feeling sick and/or vomiting, tingling in the hands and feet, insomnia, slurred speech, pneumonia, weakness, chills, fatigue, pain, dry mouth, skin rash and/or itching, swelling of the ankles, feet, or lower legs, puffy face, unusual nervousness or restlessness, confusion/disorientation, constipation, diarrhea, decreased appetite, excessive salivation, fever/shivering, urinary problems, sexual difficulties.

Uncommon: Mood or mental changes, paranoia, feeling extreme happiness (euphoria), loss of muscle coordination (ataxia), abnormally low body temperature, memory loss, continuous uncontrollable eye movements, decreased sense of taste, difficulty in swallowing, abdominal pain, hair loss, excessive sweating.

Unknown frequency: restlessness (dysphoria), abnormally slow breathing rate (bradypnea), increase in sideways curvature of the spine (scoliosis), inability to achieve or maintain an erection (erectile dysfunction).

Tell your doctor if you notice any other effect. Some side effects could be associated with the delivery system.

IMPORTANT: PLEASE READ

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 immediately seek assistance
		Only if severe	In all cases	
Common	Low Blood Pressure: dizziness, fainting, lightheadedness		√	
	Trouble breathing: Shortness of breath or unusually slow or troubled breathing		√	
Uncommon	Unusually slow heartbeat		√	
	Depression: Feeling sad, loss of interest in usual activities, hopelessness, insomnia or sleeping too much	√		
	Suicidal Behavior: thoughts or actions about hurting or killing yourself		√	
	Hallucinations: seeing or hearing things that are not real		√	

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 immediately seek
		Only if severe	In all cases	
	Trouble with vision: blurred vision, double vision		√	
Unknown	Implanted drug delivery device or infusion system malfunction can lead to withdrawal symptoms including death		√	

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

HOW TO STORE IT

Store LIORESAL IT ampoules between 15-30°C (protect from heat). Do not freeze. Do not heat sterilize.

Keep all medicines out of the reach and sight of children.

This medicine is prescribed for your specific medical problem and for your own use only. Do not give to other people.

Do not use outdated medicines. Discard them safely out of the reach of children or take them to your pharmacist who will dispose of them for you.

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
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.

MORE INFORMATION

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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