

Lioresal® Intrathecal

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Lioresal Intrathecal?

Lioresal Intrathecal contains the active ingredient baclofen. Lioresal Intrathecal is used as a muscle relaxant and to reduce tension in your muscles which may cause spasms. For more information, see Section [1. Why am I using Lioresal Intrathecal?](#) in the full CMI.

2. What should I know before I use Lioresal Intrathecal?

Do not use if you have ever had an allergic reaction to baclofen or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Lioresal Intrathecal?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Lioresal Intrathecal and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Lioresal Intrathecal?

- Lioresal Intrathecal is given by experienced doctors using special medical equipment. A small amount of Lioresal Intrathecal is injected into your spinal cord to see if it improves your muscle spasms. You will need to stay in hospital, at least at the beginning of treatment.
- If this medicine improves your condition, a special pump will be implanted under the skin of your abdomen. The pump will deliver a constant amount of Lioresal Intrathecal into your spinal cord through a tiny tube.
- You or the person caring for you will be shown how to look after the pump at home and how to keep the skin where it has been implanted free from infection.

More instructions can be found in Section [4. How do I use Lioresal Intrathecal?](#) in the full CMI.

5. What should I know while using Lioresal Intrathecal?

<p>Things you should do</p>	<ul style="list-style-type: none"> ● Remind any doctor, dentist or pharmacist you visit that you are using Lioresal Intrathecal. ● See your doctor regularly and keep all appointments to refill the pump. ● Tell your doctor immediately if you have problems with the pump. ● Tell your doctor immediately if you have thoughts of suicide or self-harm.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not stop using this medicine suddenly or allow the pump to run out of medicine.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Lioresal Intrathecal may cause dizziness, sleepiness or blurred vision in some people.
<p>Drinking alcohol</p>	<ul style="list-style-type: none"> ● Drinking alcohol while on Lioresal Intrathecal

	may make you feel more sleepy or dizzy than normal.
Looking after your medicine	<ul style="list-style-type: none"> • If you are keeping a supply of Lioresal Intrathecal at home, keep the ampoules in a cool dry place below 30°C (room temperature), away from moisture, heat or sunlight.

For more information, see Section [5. What should I know while using Lioresal Intrathecal?](#) in the full CMI.

6. Are there any side effects?

There can be serious side effects that need immediate medical attention. These include allergic reactions, infections, thoughts of suicide or self-harm, unusual changes to mood, feeling anxious, convulsions.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Lioresal® Intrathecal

Active ingredient: *baclofen*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Lioresal Intrathecal. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Lioresal Intrathecal.**

Where to find information in this leaflet:

- [1. Why am I using Lioresal Intrathecal?](#)
- [2. What should I know before I use Lioresal Intrathecal?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Lioresal Intrathecal?](#)
- [5. What should I know while using Lioresal Intrathecal?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Lioresal Intrathecal?

Lioresal Intrathecal contains the active ingredient baclofen. Lioresal Intrathecal is a muscle relaxant that is given as an injection when medicines taken by mouth do not work well enough or when they cause too many side effects.

Lioresal Intrathecal is used to reduce tension in your muscles which causes spasms. These spasms happen in various illnesses such as multiple sclerosis, cerebral palsy and other diseases or injuries of the spinal cord or brain. Lioresal Intrathecal reduces spasms and the pain that goes with them. It helps make you more mobile and improve your ability to manage your daily activities.

2. What should I know before I use Lioresal Intrathecal?

Warnings

Do not use Lioresal Intrathecal if:

- you are allergic to baclofen, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- Epilepsy that is not responding to treatment.

Check with your doctor if you have any other medical conditions, including:

- Thoughts of suicide or self-harm at any time

Speak to your doctor immediately or go to the Emergency Department of the nearest hospital for help if you have thoughts of self-harm. Ask your family, a friend or carer to monitor your behaviour and tell you if they are

worried about any changes in your behaviour. Ask them to read this leaflet.

- Infections of any kind
- Epilepsy, any history of seizures
- Parkinson's disease
- Mental illness such as schizophrenia, psychotic disorders, conditions that cause confusion
- Scoliosis, a sideways curve in the spine
- Blood circulation problems
- Heart problems
- Breathing problems
- Stomach ulcers
- Kidney problems
- History of sudden episodes of anxiety, excessive sweating, "goose-flesh", a pounding headache, an unusually slow heartbeat, stiff muscles.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Lioresal Intrathecal should not be used during pregnancy unless the expected benefit outweighs the possible risk.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if the medicine passes into breast milk.

Use in children

- The safe use of Lioresal Intrathecal in children under 4 years of age has not been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Lioresal Intrathecal and affect how it works, including:

- Levodopa, a medicine used to treat Parkinson's disease
- General anesthetics used during surgery
- Tricyclic antidepressants, a class of medicine used to treat depression
- Medicines used to lower blood pressure
- Some medicines used to reduce pain, including morphine
- Certain medicines used to help you sleep, improve your mood.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking, and if these affect Lioresal Intrathecal.

4. How do I use Lioresal Intrathecal?

How Lioresal Intrathecal is used

This medicine 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 the skin of your abdomen. From the pump, a constant amount of baclofen goes into your spinal cord through a tiny tube. The pump will give you a small amount of medicine all the time.

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.

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

How to monitor at home

You or the person caring for you will be shown how to look after the pump at home and how to keep the skin where it has been implanted free from infection.

Your doctor will want to see you regularly to check your progress, adjust the dose of Lioresal Intrathecal if needed, and make sure your pump is working well.

If you use too much Lioresal Intrathecal

If you think that you have received too much Lioresal Intrathecal, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

It is very important that you and those caring for you know the signs of overdose that can happen. These are:

- unusual muscle weakness
- unusual sleepiness
- unusual light-headedness or dizziness
- unusual nausea or vomiting
- excessive saliva

- breathing problems
- fainting or fits (seizures).

If you have any of the above signs, inform your doctor without delay.

Signs of overdose may happen suddenly or more slowly (for example, because the pump is not working properly).

If the medicine must be stopped

If you need to stop using this medicine, your doctor will reduce the dose slowly to avoid unwanted side effects. Stopping Lioresal Intrathecal suddenly or reducing the dose quickly can cause serious side effects which in a few, rare cases have been fatal.

5. What should I know while using Lioresal Intrathecal?

Things you should do

Follow your doctor's instructions carefully. Make sure the pump and the site on the skin are looked after properly.

If not, the pump may not work properly or you could get a serious skin infection.

See your doctor regularly and keep all appointments to refill the pump.

If you don't have the pump refilled when you are supposed to, you may suddenly run out of medicine (see "Things you should not do" for more information).

If the flow rate (the amount of medicine you are given each day through the pump) needs to be changed, make sure this is supervised by a trained health professional.

Errors in changing the flow rate could make the dose of medicine too high or low and lead to serious side effects.

Call your doctor straight away if you:

- Have any thoughts of suicide or unusual changes in behaviour;
- Think your muscle spasms are returning or getting worse. Your doctor may be able to change the dose of Lioresal Intrathecal to make it work better for you.
- Feel pain in your back, shoulders, neck or bottom;
- Become pregnant while taking this medicine. Your doctor can discuss with you the benefits and risks of using this medicine while you are pregnant.

Tell any doctor, dentist or pharmacist you visit that you are using Lioresal Intrathecal.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are having Lioresal Intrathecal.

Things you should not do

Do not stop Lioresal Intrathecal suddenly or allow the pump to run out of medicine. If it should happen, tell your doctor immediately and watch out for the following symptoms.

Stopping this medicine suddenly may bring on severe and uncontrolled muscle spasms and other unwanted symptoms, including difficulty in muscle movements, dizziness or light-headedness due to low blood pressure, severe itching and numbness or tingling in hands and feet, high fever, fast heartbeat, changes to your mental state, for example anxiety, agitation, confusion, hallucination, abnormal thinking and behaviour, and convulsions (seizures), persistent painful erection of the penis (priapism) and infection (sepsis).

Problems with the pump, for example, due to battery problems, catheter problems, alarm dysfunction or device malfunctions may also cause withdrawal symptoms.

If you have any of the above signs, tell your doctor immediately. These signs may be followed by more serious side effects (including death) unless you are treated immediately.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Lioresal Intrathecal affects you.

Lioresal Intrathecal may cause dizziness, sleepiness or blurred vision in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may make you feel more sleepy or dizzy than normal.

Looking after your medicine

If you are keeping a supply of Lioresal Intrathecal at home:

- Keep your ampoules in the cardboard carton until it is time to use them.
- Store the ampoules in a cool dry place below 30°C. (room temperature), away from moisture, heat or sunlight; for example, do not store it in the bathroom or near a sink, or in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>General</p> <ul style="list-style-type: none">• drowsiness, tiredness or lack of energy• dizziness or light-headedness• headache• slurred speech• blurred or double vision• problems with concentration or memory• problems with sexual function• hair loss. <p>Stomach related</p> <ul style="list-style-type: none">• feeling sick or vomiting	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● loss of appetite, weight loss ● constipation, diarrhoea ● dry mouth, decreased sense of taste, increase in saliva ● difficulty swallowing. <p>Muscle related</p> <ul style="list-style-type: none"> ● numbness or tingling in the hands and feet ● muscle weakness, spasms or pain or change in muscle tone ● problems with coordination and balance. 	

Serious side effects

Serious side effects	What to do
<p>Mood related</p> <ul style="list-style-type: none"> ● feeling anxious, confused, disorientated or unable to sleep ● depression or unusual changes to mood, feeling of being watched 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● feeling of extreme happiness (euphoria) ● thoughts of suicide or self-harm ● hallucinations ● extreme sleepiness. <p>Signs of allergic reaction</p> <ul style="list-style-type: none"> ● slow or difficult breathing, chest tightness or congestion ● swelling of the face, ankles, feet or lower legs ● rash or itching of skin. <p>Stomach related</p> <ul style="list-style-type: none"> ● severe vomiting, diarrhoea or constipation ● loss of bladder (urine) control or other bladder problems. <p>Other</p> <ul style="list-style-type: none"> ● fever, chills or other signs of infection, pneumonia ● pain, numbness or heavy feeling in the legs 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● unusually slow heart beat ● seizures (fits) ● continuous uncontrollable eye movements ● increase in sideways curvature of the spine (a type of spinal deformity called scoliosis). 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Lioresal Intrathecal contains

Active ingredient (main ingredient)	baclofen
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• sodium chloride• water for injection. Lioresal Intrathecal does not contain preservatives.
Potential allergens	None.

Do not take this medicine if you are allergic to any of these ingredients.

What Lioresal Intrathecal looks like

Lioresal Intrathecal is packaged in clear glass ampoules, each pack contains one ampoule. There are different sizes of ampoule available:

- 1 mL ampoule containing 0.05 mg (50 micrograms) baclofen, Aust R 53837
- 5 mL ampoule containing 10 mg baclofen, Aust R 53836

- 20 mL ampoule containing 10 mg baclofen, Aust R 53835.

The 1 mL ampoule is used to test your response to Lioresal Intrathecal. The two larger sizes are used to fill the pump, depending on the amount of medicine you need.

Who distributes Lioresal Intrathecal

Lioresal Intrathecal is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1 800 671 203

Website: www.novartis.com.au

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This leaflet was prepared in February 2024.

Internal document code: (Irsi220224c) based on PI (Irsi220224i)