

Lioresal[®] Intrathecal

baclofen

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Lioresal Intrathecal.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine. You can also download the most up-to-date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware. All medicines have risks and benefits. Your doctor has weighed the risks of you having Lioresal Intrathecal against the benefits they expect it will give you.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Lioresal Intrathecal is used for

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.

Because this medicine reduces spasms and the pain that goes with them, it helps to make you more mobile. This helps you to manage your daily activities and makes physiotherapy easier.

Lioresal Intrathecal belongs to a group of medicines called muscle relaxants. It contains the active ingredient, baclofen, in the form of an ampoule for injection. It is used when medicines taken by mouth do not work well enough or when they cause too many side effects.

The solution in the ampoule is injected into your back (spinal cord) using a special pump. From the pump, a constant amount of baclofen goes into your spinal cord through a tiny tube.

This medicine can be used for adults and for children aged four years or older.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another purpose.

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

Before you have Lioresal Intrathecal

When you must not have it

Do not have Lioresal Intrathecal if you have ever had an allergic reaction after taking:

- baclofen (the active ingredient in Lioresal Intrathecal and Lioresal tablets)
- any of the other ingredients listed at the end of this leaflet

Symptoms of an allergic reaction may include hives or an itchy skin rash, flushing of the face, swelling of the face, lips or tongue, faintness, tight feeling in the chest, wheezing or difficulty breathing.

Do not have Lioresal Intrathecal after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

If you are not sure whether you should start having this medicine, talk to your doctor.

Before you start to have it

Tell your doctor if you are pregnant or breast-feeding. Ask your doctor about the risks and benefits involved.

There is no information on use of this medicine in pregnancy or while breast-feeding.

Get urgent medical help if you observe that your implanted device is not working and you also notice withdrawal symptoms (see "If the medicine must be stopped").

Tell your doctor if you have any of the following medical conditions:

- an infection of any kind
- epilepsy (seizures)
- a mental illness, especially if it makes you feel confused at times
- heart disease
- kidney disease

- liver disease
- breathing problems
- stomach ulcers now or at any time in the past
- Parkinson's disease
- problems with blood flow to the brain

Your doctor may not want to give you this medicine or may want to take special precautions if you have any of the above conditions.

If you have not told your doctor about any of these things, tell him/her before you start Lioresal Intrathecal.

Taking other medicines

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

Some medicines and Lioresal Intrathecal may interfere with each other. These include:

- medicines for high blood pressure
- medicines to help you sleep or calm you down
- medicines for depression (sad mood)
- medicines for pain such as morphine
- medicines for Parkinson's disease

You may need to take different amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are having Lioresal Intrathecal.

How Lioresal Intrathecal is given

What will happen

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. 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.

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.

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.

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

If you have too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you may have had too much Lioresal Intrathecal, 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 this medicine must be stopped for any reason, your doctor will reduce the dose gradually to avoid unwanted side effects. Suddenly stopping Lioresal Intrathecal or rapidly reducing the dose can cause serious side effects which in a few, rare cases have been fatal.

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, anxiety, high fever, altered mental conditions for example agitation, confusion, hallucination, abnormal thinking and behaviour or 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.

While you are having Lioresal Intrathecal

Things you must 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 "If the medicine must be stopped" for more information).

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

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

If your muscle spasms come back, either suddenly or gradually, tell your doctor.

Your doctor may be able to change the dose of Lioresal Intrathecal to make it work better for you.

Tell your doctor immediately if you have pain in your back, shoulders, neck and buttock during treatment.

If you become pregnant while you are having this medicine, tell your doctor.

You doctor can discuss with you the risks of being given this medicine while you are pregnant.

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

Tell any other doctor, dentist or pharmacist who treats you that you are having Lioresal Intrathecal.

Things you must not do

Do not stop Lioresal Intrathecal suddenly.

See "If the medicine must be stopped" for more information.

Do not give this medicine to anyone else, even if their symptoms seem to be the same as yours.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are having Lioresal Intrathecal until you know how it affects you.

This medicine may cause dizziness, sleepiness or blurred vision in some people.

Be careful when drinking alcohol while you are having this medicine.

You may feel more sleepy or dizzy than usual.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are having Lioresal Intrathecal.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Some side effects could be associated with the delivery system.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- drowsiness, tiredness or lack of energy
- dizziness or light-headedness
- headache
- feeling sick or vomiting
- loss of appetite, weight loss
- constipation
- numbness or tingling in the hands and feet
- muscle weakness, spasms or pain or change in muscle tone
- problems with coordination and balance
- slurred speech
- blurred or double vision
- feeling anxious, confused, disorientated or unable to sleep
- problems with concentration or memory
- dry mouth, decreased sense of taste
- diarrhoea
- increase in saliva
- problems with sexual function
- hair loss

Tell your doctor immediately if you notice any of the following:

- slow or difficult breathing, chest tightness or congestion
- fever, chills or other signs of infection, pneumonia
- swelling of the face, ankles, feet or lower legs
- pain, numbness or heavy feeling in the legs
- unusually slow heart beat
- seizures (fits)
- depression or other severe mood or mental disorders (paranoia)
- difficulty in swallowing
- rash or itching of skin
- continuous uncontrollable eye movements
- loss of bladder (urine) control or other bladder problems
- severe vomiting, diarrhoea or constipation

- increase in sideways curvature of the spine (a type of spinal deformity called scoliosis)
- feeling of extreme happiness (euphoria)
- confusion, disorientation
- suicidal ideas and suicide attempt
- hallucinations
- extreme sleepiness

The above side effects could be serious. You may need medical attention.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Some people may get other side effects of Lioresal Intrathecal.

After being given Lioresal Intrathecal

Storage

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 degrees C. (room temperature)
- Do not store this medicine or any other medicine in the bathroom or near a sink
- Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines. Lioresal Intrathecal will keep well if it is cool and dry.

Keep the ampoules where young children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If you no longer need this medicine or it has passed its expiry date,

return any unused ampoules to your pharmacist.

10 mg/20 mL - AUST R 53835

Internal document code:

(Irsi011117c) based on PI

(Irsi011117i)

Product description

What it looks like

Lioresal Intrathecal is packaged in clear glass ampoules in packs of one ampoule. There are different sizes of ampoule available:

- 1 mL ampoule containing 0.05 mg (50 micrograms) baclofen.
- 5 mL ampoule containing 10 mg baclofen.
- 20 mL ampoule containing 10 mg baclofen.

The smallest size 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.

Ingredients

As well as baclofen, the active ingredient, the ampoules also contain sodium chloride and water for injection.

Sponsor

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

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This leaflet was prepared in November 2017.

Australian Registration Numbers

Lioresal Intrathecal:

0.05 mg/1 mL - AUST R 53837

10 mg/5 mL - AUST R 53836