

Sintetica Baclofen Intrathecal

Intrathecal Injection

Baclofen

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you are given Sintetica Baclofen Intrathecal.

This leaflet answers some common questions about Sintetica Baclofen Intrathecal. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.ebs.tga.gov.au.

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of giving you Sintetica Baclofen Intrathecal against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may want to read it again.

What Sintetica Baclofen Intrathecal is used for

Sintetica Baclofen 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.

Sintetica Baclofen Intrathecal belongs to a group of medicines called muscle relaxants. It contains the active ingredient, baclofen, in a solution for injection or infusion. 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 canal) using a special pump. From the pump, a constant amount of baclofen goes into the space surrounding your spinal cord through a tiny tube.

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

Your doctor may have prescribed this medicine for another reason.

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

Sintetica Baclofen Intrathecal is only available with a doctor's prescription. Sintetica Baclofen Intrathecal is not addictive.

Before you are given Sintetica Baclofen Intrathecal

Sintetica Baclofen Intrathecal is not suitable for everyone.

When you must not be given it

You must not be given Sintetica Baclofen Intrathecal if you have epilepsy not controlled by treatment, e.g. if you continue to have fits or convulsions despite medication.

You must not be given Sintetica Baclofen Intrathecal if you are allergic to any medicine containing baclofen or any of the 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.

Sintetica Baclofen Intrathecal must not be used after the expiry date (EXP) printed on the pack, or if the packaging is torn or shows signs of tampering. The solution must be clear before use.

If you are not sure whether you should be given Sintetica Baclofen Intrathecal, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

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 or have had any medical conditions, especially the following:

- an infection of any kind
- schizophrenia or other mental illness, especially if it makes you feel confused at times
- Parkinson's disease
- seizures due to epilepsy or any other reason
- autonomic dysreflexia, an emergency condition associated with extremely high blood pressure, intense headaches, profuse sweating, blurred vision and other symptoms
- problems with blood flow to the brain
- heart or lung disease
- kidney disease
- liver disease
- breathing problems
- stomach ulcer now or at any time in the past
- 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. 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.

Your doctor may need to do tests, e.g. spinal imaging, before treating you with Sintetica Baclofen Intrathecal to check if there is any reason you should not be given it.

Tell your doctor if you are pregnant or breastfeeding.

There are no studies using Sintetica Baclofen Intrathecal in women who are pregnant or breastfeeding. Your doctor will discuss the possible risks and benefits of you being given Sintetica Baclofen Intrathecal during pregnancy and breastfeeding.

Tell your doctor if you are over 65 years old.

Elderly persons may be more sensitive to side effects which your doctor can manage by changing the dose gradually.

If you have not told your doctor or pharmacist about any of the above, tell them before you are given Sintetica Baclofen Intrathecal.

Taking other medicines

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

Tell any healthcare professional who is prescribing a new medicine for you that you are using Sintetica Baclofen Intrathecal.

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

- levodopa, carbidopa and other similar medicines known as DDC inhibitors (used to treat Parkinson's disease)
- general anaesthetics used to put you to sleep during surgery, such as fentanyl and propofol
- morphine or other opiates, used to control pain
- some antidepressants, known as tricyclics
- medicines used to treat high blood pressure
- benzodiazepines, used to treat anxiety, insomnia, seizures or muscle spasms
- any medicine or drug which affects the Central Nervous System (brain or spinal cord).

The above medicines may be affected by Sintetica Baclofen

Intrathecal, or may affect how well it works. You may need different amounts of Sintetica Baclofen Intrathecal or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Sintetica Baclofen Intrathecal.

How Sintetica Baclofen Intrathecal is given

How it is given

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 Sintetica Baclofen Intrathecal into your spinal canal 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 after the first injection and following pump implant. You will be assessed after each change of dose for possible side effects or evidence of infection. The functioning of the pump 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.

How much will be given

Your doctor will decide how much Sintetica Baclofen Intrathecal you will be given. 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.

This dose will depend on your condition and how your body responds to the treatment. It is usually between 276-800 micrograms a day. Children under 12 years of age usually require lower doses than older patients.

Ask your doctor or pharmacist if you would like more information about how your dose is managed.

How often you will be given it

Your doctor will work out how often you need to return to have the pump filled with additional Sintetica Baclofen Intrathecal before it runs out. It is important that the pump not be allowed to run out because you can have a serious reaction if you stop treatment suddenly.

Follow closely the instructions given to you by the hospital staff and discuss with your doctor first before changing any of your treatment appointments.

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 Sintetica Baclofen Intrathecal or rapidly reducing the dose can cause serious side effects which in a few rare cases have been fatal.

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

These symptoms can lead to more severe side effects unless treated immediately.

Stopping this medicine suddenly may cause:

- severe and uncontrolled muscle spasms
- difficulty in muscle movements
- dizziness or light-headedness due to low blood pressure
- severe itching and numbness or tingling in hands and feet
- convulsions (seizures)
- persistent painful erection of the penis (priapism)
- high fever
- altered mental conditions, for example anxiety, 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 using Sintetica Baclofen Intrathecal

Things you must do

Follow your doctor's instructions carefully. Make sure the pump and the site where the pump was inserted are looked after properly.

If not, the pump may not work properly or you could get a serious skin infection. If you're not sure what to do, or if you're not sure if there's a problem, talk to your doctor.

Keep all of your doctor's appointments so that your medicine can be refilled and your progress can be checked.

It is very important that your pump is refilled before your medicine runs out as it is not safe to stop treatment suddenly. Also, your doctor needs to check on your progress to make sure you are on the right dose.

See your doctor if you feel that your condition is not improving or is getting worse.

Your dose may need adjusting or there might be a problem with the pump.

If any adjustments to the pump are needed, including to the pump flow rate (dose), make sure this is supervised by a doctor.

Errors in adjusting the pump can 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 Sintetica Baclofen 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.

See your doctor immediately if your condition is worsening and you experience unusual itching, dizziness, light-headedness or tingling in the hands or feet.

There may be a problem with the pump that is stopping you getting your medicine. This can be life-threatening and you may need immediate medical attention.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Sintetica Baclofen Intrathecal. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are being given this medicine.

If you are going to have surgery, tell the surgeon and anaesthetist that you are using this medicine.

It may affect other medicines used during surgery.

If you become pregnant while using this medicine, tell your doctor immediately.

Things you must not do

Do not stop Baclofen Sintetica 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 or operating machinery until you know how Sintetica Baclofen Intrathecal affects you.

It may cause sleepiness, dizziness, problems with coordination or vision, and hallucinations in some people. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel less alert. If you drink alcohol, or take strong pain killers or barbiturates, the effects may be worse.

Be careful drinking alcohol until you know how Sintetica Baclofen Intrathecal affects you.

Alcohol may have a greater effect on you if you are being treated with Sintetica Baclofen Intrathecal. You may feel more sleepy or dizzy than usual.

Be careful on stairs and uneven surfaces to avoid falling.

Sintetica Baclofen Intrathecal works by reducing muscle tone. It may cause weakness and affect reflexes and coordination. Talk to your doctor if you are having problems as they may need to change your dose.

In case of overdose

If you are given too much

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go

to Accident and Emergency at your nearest hospital, if you think that you may have been given too much Sintetica Baclofen Intrathecal.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

People vary in their sensitivity to Sintetica Baclofen Intrathecal. Some people may have signs of overdose at doses that are safe for other people.

Take care particularly at the start of treatment, after a dose change or after restarting treatment if you have had a break.

It is very important that you and those caring for you know the signs of overdose that can happen. Symptoms of an overdose may include extreme weakness, unusual drowsiness, light-headedness, dizziness, sleepiness, excessive saliva, nausea or vomiting. More severe symptoms include fits, difficulty breathing, slow heartbeat, loss of consciousness, coma and death.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Sintetica Baclofen Intrathecal.

Like all medicines, Sintetica Baclofen Intrathecal may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Some side effects could be associated with the delivery system.

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 feeling light-headed
- 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, or chest tightness, pain 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 or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After being given Sintetica Baclofen Intrathecal

Storage

Sintetica Baclofen Intrathecal will be stored in the pharmacy or on the ward under the recommended storage conditions.

It must be kept in a cool dry place, protected from light, where the temperature stays below 25°C. Do not refrigerate or freeze.

Disposal

Any Sintetica Baclofen Intrathecal which has passed its expiry date, or is left in the container after use, will be disposed of in a safe manner by your doctor, nurse or pharmacist.

Product description

What it looks like

Sintetica Baclofen Intrathecal is a clear, colourless solution for injection or infusion. It is available in clear glass ampoules in the following sizes:

- 1 mL containing 50 microgram baclofen - 10 ampoules in each pack
- 5 mL containing 10 mg baclofen - 1 ampoule and 10 ampoules in each pack
- 20 mL containing 10 mg baclofen - 1 ampoule in each pack
- 20 mL containing 40 mg baclofen - 1 ampoule in each pack.

Not all presentations may be marketed.

Ingredients

Active ingredient:

- baclofen

Inactive ingredients:

- sodium chloride
- water for injections.

Sponsor details

Boucher & Muir Pty Ltd
 Level 9, 76 Berry Street
 North Sydney NSW 2060
 Ph: 1800 627 680

Sintetica Baclofen Intrathecal:
 50 microgram/1 mL: AUST R 271172
 10 mg/20 mL: AUST R 271173
 10 mg/5 mL: AUST R 271174
 40 mg/20 mL: AUST R 271175

Date of preparation

This leaflet was prepared on 17 November 2020.