

# Sintetica Baclofen 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 Sintetica Baclofen Intrathecal?

Sintetica Baclofen Intrathecal contains the active ingredient baclofen. Sintetica Baclofen 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 Sintetica Baclofen Intrathecal?](#) in the full CMI.

### 2. What should I know before I use Sintetica Baclofen 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 Sintetica Baclofen Intrathecal?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Sintetica Baclofen 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 Sintetica Baclofen Intrathecal?

Sintetica Baclofen Intrathecal is given by experienced doctors using special medical equipment. A small amount of Sintetica Baclofen 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 Sintetica Baclofen 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 Sintetica Baclofen Intrathecal?](#) in the full CMI.

### 5. What should I know while using Sintetica Baclofen Intrathecal?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking Sintetica Baclofen Intrathecal</li><li>• Keep all of your doctor's appointments so that your medicine can be refilled and your progress can be checked.</li><li>• Tell your doctor immediately if you have problems with the pump.</li><li>• Tell your doctor immediately if you have thoughts of suicide or self-harm.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly or allow the pump to run out of medicine.</li><li>• Do not give this medicine to anyone else, even if their symptoms seem to be the same as yours.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Sintetica Baclofen Intrathecal may cause dizziness, sleepiness problems with coordination or vision, and hallucinations in some people.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Drinking alcohol while on Sintetica Baclofen Intrathecal may make you feel more sleepy or dizzy than normal.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• 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.</li></ul>

For more information, see Section [5. What should I know while using Sintetica Baclofen 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.

# Sintetica Baclofen Intrathecal

Active ingredient: *baclofen*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Sintetica Baclofen 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 Sintetica Baclofen Intrathecal.**

Where to find information in this leaflet:

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

## 1. Why am I using Sintetica Baclofen Intrathecal?

Sintetica Baclofen Intrathecal contains the active ingredient **baclofen**. Sintetica Baclofen 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.

**Sintetica Baclofen Intrathecal is used to reduce tension in your muscles which causes spasm.** These spasms happen in various illnesses such as multiple sclerosis, cerebral palsy and other diseases or injuries of the spinal cord or brain.

Sintetica Baclofen Intrathecal reduces spasm 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 Sintetica Baclofen Intrathecal?

### Warnings

**Do not use Sintetica Baclofen 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 or lung problems
- Breathing problems
- Stomach ulcers now or at any time in the past
- Kidney problems
- Liver disease
- 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. Sintetica Baclofen 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 Sintetica Baclofen Intrathecal in children under 4 years of age has not been established.

## Use in elderly

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

## 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 Sintetica Baclofen Intrathecal and affect how it works, including:**

- levodopa, carbidopa and other similar medicines known as DDC inhibitors (used to treat Parkinson's disease)
- General anesthetics used
- 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 benzodiazepines, used to treat anxiety, insomnia, seizures or muscle spasms.
- any medicine or drug which affects the Central Nervous System (brain or spinal cord).

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

## 4. How do I use Sintetica Baclofen Intrathecal?

### How to use Sintetica Baclofen Intrathecal

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 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

Sintetica Baclofen Intrathecal should be used 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 Sintetica Baclofen Intrathecal if needed and make sure your pump is working well.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

## If you use too much Sintetica Baclofen Intrathecal

If you think that you have used too much Sintetica Baclofen 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 Sintetica Baclofen 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 Sintetica Baclofen 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:

- 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 heartbeat
- 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
- Become pregnant while taking this medicine. Your doctor can discuss with you the benefits and risks of using this medicine while you are pregnant.

Remind any doctor, dentist or pharmacist you visit that you are using Sintetica Baclofen Intrathecal.

## Things you should not do

**Do not stop Baclofen Sintetica Intrathecal suddenly. 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.

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

## Driving or using machines

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

Sintetica Baclofen Intrathecal may cause dizziness sleepiness or blurred vision in some people.

## Drinking alcohol

**Tell your doctor if you drink alcohol.**

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 normal.

## Looking after your medicine

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.**

**Keep it where young children cannot reach it.**

## Getting rid of any unwanted medicine

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.

## 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><b>General</b></p> <ul style="list-style-type: none"><li>• drowsiness, tiredness or lack of energy</li><li>• dizziness or light-headedness</li><li>• headache</li><li>• slurred speech</li><li>• blurred or double vision</li><li>• problems with concentration or memory</li><li>• problems with sexual function</li><li>• hair loss.</li></ul> <p><b>Stomach related</b></p> <ul style="list-style-type: none"><li>• feeling sick or vomiting</li><li>• loss of appetite, weight loss</li><li>• constipation, diarrhoea</li><li>• dry mouth, decreased sense of taste, increase in saliva</li><li>• difficulty swallowing.</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<p><b>Muscle related</b></p> <ul style="list-style-type: none"> <li>numbness or tingling in the hands and feet</li> <li>muscle weakness, spasms or pain or change in muscle tone</li> <li>problems with coordination and balance.</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<p><b>Mood related</b></p> <ul style="list-style-type: none"> <li>feeling anxious, confused, disorientated or unable to sleep</li> <li>depression or unusual changes to mood, feeling of being watched</li> <li>feeling of extreme happiness (euphoria)</li> <li>thoughts of suicide or self-harm</li> <li>hallucinations</li> <li>extreme sleepiness.</li> </ul> <p><b>Signs of allergic reaction</b></p> <ul style="list-style-type: none"> <li>slow or difficult breathing, chest tightness or congestion</li> <li>swelling of the face, ankles, feet or lower legs</li> <li>rash or itching of skin.</li> </ul> <p><b>Stomach related</b></p> <ul style="list-style-type: none"> <li>severe vomiting, diarrhoea or constipation</li> <li>loss of bladder (urine) control or other bladder problems.</li> </ul> <p><b>Other</b></p> <ul style="list-style-type: none"> <li>fever, chills or other signs of infection, pneumonia</li> <li>pain, numbness or heavy feeling in the legs</li> <li>unusually slow heartbeat</li> <li>seizures (fits)</li> <li>continuous uncontrollable eye movements</li> <li>increase in sideways curvature of the spine (a type of spinal deformity called scoliosis).</li> </ul>	<p><b>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.</b></p>

**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](http://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 Sintetica Baclofen Intrathecal contains

<b>Active ingredient (main ingredient)</b>	Baclofen
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride Water for injections. Sintetica Baclofen Intrathecal does not contain preservatives.
<b>Potential allergens</b>	None.

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

### What Sintetica Baclofen Intrathecal 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.

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

### Who distributes Sintetica Baclofen Intrathecal

Boucher & Muir Pty Ltd

Level 9, 76 Berry Street

North Sydney NSW 2060

Ph: 1800 627 680

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