

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is to be supplied by doctor's prescription only

Baclofen Sintetica 2mg/ml

Solution for intrathecal infusion

Active ingredient

1 ml contains 2mg baclofen

Inactive ingredients and allergens: See section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains essential information about this medicine. If you have any further questions, refer to the doctor or the pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

1. What is this medicine used for?

Adults:

For the treatment of patients with severe chronic spasticity resulting from trauma, multiple sclerosis or other spinal cord disorders, who are unresponsive to oral baclofen or other orally administered antispastic agents and/or those patients who experience unacceptable side effects at effective oral doses.

Baclofen Sintetica is effective in patients with severe chronic spasticity of cerebral origin, resulting e.g. from cerebral palsy, brain trauma or cerebrovascular accident (clinical experience with the treatment of those cases is limited).

Children:

For the treatment of children aged 4 years and above with severe chronic spasticity of cerebral origin or of spinal origin (associated with injury, multiple sclerosis, or other spinal cord diseases) who are unresponsive to oral baclofen or to other orally administered antispastics and/or to patients who experience unacceptable side effects at effective oral doses.

Therapeutic group: muscle relaxant

2. Before using this medicine

Do not use this medicine if:

You are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains (see section 6).

Special warnings regarding the use of this medicine

- It is important to make sure that there are no problems with the pump. Get urgent medical help if you observe that the pump is not working and you also notice withdrawal symptoms (see section 3, 'How should you use the medicine?').
- Treatment with Baclofen Sintetica must not stop suddenly because of the risk of withdrawal effects. You must make sure that you do not miss those hospital visits at which the pump reservoir is being refilled.
- Your doctor may want to give you a checkup from time to time while you are being treated with Baclofen Sintetica.
- If you are going to have an operation of any kind, make sure that the doctor knows that you are being treated with Baclofen Sintetica.
Anaesthetics such as propofol may increase the risk of side effects.

Before the treatment with Baclofen Sintetica, tell your doctor if:

- you are having any other injections into the spine
- you are suffering from any infection
- you had a head injury within the last year
- you ever had a crisis caused by a condition called autonomic dysreflexia (Your doctor will be able to explain this to you)
- you have had a stroke
- you have epilepsy

- you have a stomach ulcer or any other problem with your digestion
- you suffer from any mental illness
- you are being treated for high blood pressure
- you have Parkinson's disease
- you suffer from any liver, kidney or lung disease
- you have diabetes
- you have difficulties in urinating
- you are pregnant or breast feeding

If you suffer from any of the above, tell your doctor or nurse because Baclofen Sintetica may not be the right medicine for you.

Tell your doctor immediately if you get any of these symptoms during treatment with Baclofen Sintetica:

- **If you have pain** in the back, shoulders, neck and buttock during the treatment (a type of spinal deformity called scoliosis).
- **If you have** thoughts of harming or killing yourself at any time, speak to your doctor straightaway or go to a hospital. Also, ask a relative or close friend to tell you if they are worried about any changes in your behaviour and ask them to read this leaflet.

Children and adolescents

The medicine is intended for adults and children aged 4 years and above.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, inform your doctor or pharmacist. In particular if you are taking:

- Other medicines for your spastic condition e.g. tizanidine or diazepam
- Antidepressants e.g. imipramine or amitriptyline
- Medicines for high blood pressure e.g. diltiazem or moxonidine
- Other drugs which also affect the kidney, e.g. ibuprofen
- Medicines for Parkinson's disease e.g. levodopa or carbidopa
- Medicines for epilepsy e.g. carbamazepine or clonazepam
- Opiates for pain relief e.g. morphine
- Medicines which slow down the nervous system, e.g. anti-histamines such as promethazine and sedatives such as temazepam. (some of these can be bought without prescription)

Using the medicine and alcohol consumption

Be careful when drinking alcohol, it may affect you more than usual.

Pregnancy and breastfeeding

If you are pregnant, planning to get pregnant or breast-feeding, do not use this medicine without consulting your doctor before starting treatment.

If you are pregnant or breast-feeding, consult a doctor or pharmacist before taking medicines.

Driving and using machines

Some people may feel drowsy and/or dizzy or have problems with their eyes while they are being treated with Baclofen Sintetica. If this happens, you should not drive or do anything that requires you to be alert (such as operate tools or machinery) until these effects have worn off.

Important information about some of the medicine's ingredients

This medicinal product contains less than 1 mmol sodium (23 mg) per maximum daily dose, so it is essentially "sodium-free".

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. You should check with the doctor or the pharmacist if you are unsure about your dose and about how to take this medicine. The dosage and treatment will be determined only by the doctor.

Baclofen Sintetica is administered by intrathecal injection. This means that the medicine is injected directly into the spinal fluid. The dose needed varies from person to person depending on their condition, and the doctor will decide what dose you need after he/she has tested your response to the drug.

First of all, the doctor will find out, by giving you single doses of Baclofen Sintetica, whether it is suitable for you. During this period your heart and lung functions will be closely monitored. If your symptoms improve, a special pump which can deliver the drug continuously, will be implanted into your chest or abdominal wall. The doctor will give you all of the information you need to use the pump and to get the correct dosage. Make sure that you fully understand all the instructions.

The final dose of Baclofen Sintetica depends on how each person responds to the drug. You will be started on a low dose, and this will be increased gradually over a few days, under the supervision of the doctor, until you are having the dose which is right for you. If the starting dose is too high, or if the dose is increased too quickly, you are more likely to experience side effects.

To avoid unpleasant side effects which may be serious and even life-threatening, it is important that your pump does not run out. The pump must always be filled by a doctor or nurse, and you must make sure that you do not miss your clinic appointments.

During long-term treatment some patients find that Baclofen Sintetica becomes less effective. You may require occasional breaks in treatment. Your doctor will advise you what to do.

Do not exceed the recommended dose.

If you use more Baclofen Sintetica than you should

It is very important that you, and anyone caring for you, can recognize the signs of overdose.

These may appear if the pump is not working properly, and you must tell the doctor straight away.

Signs of overdose are:

- Unusual muscle weakness (too little muscle tone)
- Sleepiness
- Dizziness or light-headedness
- Excessive salivation
- Nausea or vomiting
- Difficulty in breathing
- Convulsions
- Loss of consciousness
- Abnormally low body temperature

If you stop using Baclofen Sintetica

You should not stop treatment suddenly. If the doctor decides to stop your treatment, the dose will be reduced gradually to prevent withdrawal symptoms such as muscle spasms and increased muscle rigidity, fast heart rate, fever, confusion, hallucinations, changes in mood and emotion, mental disorders, feeling persecuted or convulsions (fits), persistent and painful erection (priapism). On rare occasions these symptoms could be life-threatening. If you or your caregiver notice any of these symptoms, contact your doctor immediately just in case something has gone wrong with the pump or delivery system.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, Baclofen Sintetica may cause side effects in some patients. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Implanted drug delivery device or infusion system malfunction can lead to withdrawal symptoms including death.

Very common side effects – affect more than one user out of ten

- Feeling tired, drowsy or weak

Common side effects – affect up to one user out of 10

- Feeling lethargic (having no energy)
- Headache, dizziness or light-headedness
- Pain, fever or chills
- Seizures
- Tingling hands or feet
- Problems with eyesight
- Slurred speech
- Insomnia
- Breathing difficulties, pneumonia
- Feeling confused, anxious, agitated or depressed

- Low blood pressure (fainting)
- Feeling or being sick, constipation and diarrhoea
- Loss of appetite, dry mouth or excessive saliva
- Rash and itching, swelling of the face or hands and feet
- Urinary incontinence, or problems when urinating
- Cramps
- Sexual problems in men, e.g. impotence

Uncommon side effects – affect up to one user out of 100

- Feeling abnormally cold
- Memory loss
- Mood swings and hallucinations, feeling suicidal
- Stomach ache, difficulty in swallowing, loss of taste, dehydration
- Loss of muscle control
- Raised blood pressure
- Slow heartbeat
- Deep vein thrombosis
- Flushed or pale skin, excessive sweating
- Hair loss

Side effects of unknown frequency (frequency has not been determined yet)

- Restlessness
- Abnormally slow breathing rate
- Increase in sideways curvature of the spine (scoliosis)
- Inability to achieve or maintain an erection (erectile dysfunction)

There have been rare reports of problems associated with the pump and delivery system e.g. infections, inflammation of the lining around the brain and spinal cord (meningitis) or a collection of immune cells at the tip of the delivery tube.

If any of the symptoms become troublesome, if side effect gets worse, or if you experience a side effect not mentioned in the leaflet, you should consult the doctor. He may want to adjust the dose or give you a different medicine.

Reporting side effects

You can report side effects to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Medication' on the MoH home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. Date) appearing on the outer carton and the ampoule. The expiry date refers to the last day of that month.

Storage conditions

- Store below 25°C. Do not refrigerate or freeze.
- Store in the original package in order to protect from light.
- After opening, the product must be used immediately. Any remaining product not administered to the pump must be disposed of.

6. Additional information

In addition to the active ingredient the medicine also contains:

Sodium chloride, water for injection.

What does the medicine look like and what are the contents of the package:

Clear and colorless solution in ampoules.

Baclofen Sintetica 10mg/5ml:

1 ampoule with 5 ml solution contains 10 mg of baclofen. The ampoule is made of clear colorless glass. Each pack contains 10 ampoules.

Baclofen Sintetica 40mg/20ml:

1 ampoule with 20 ml solution contains 40 mg of baclofen. The ampoule is made of clear colorless glass.

Each pack contains 1 ampoule.

Not all pack sizes may be marketed.

Registration holder's name and address: Biomed-JR Ltd., Hayasmin St. 28, Tel mond.

Manufacturer's name and address: Sintetica SA, Via Penate 5, CH-6850 Mendrisio, Switzerland

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 156-85-34288