

Package leaflet: Information for the patient

Baclopar 10 mg Tablets (baclofen)

Read all of this leaflet carefully before you or your child start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Baclopar is and what it is used for
2. What you need to know before you take Baclopar
3. How to take Baclopar
4. Possible side effects
5. How to store Baclopar
6. Contents of the pack and other information

1. What Baclopar is and what it is used for

Baclopar contains the active ingredient, baclofen. Baclofen is a muscle-relaxant drug belonging to a group of medicines called antispasticity agents. Baclopar is used to reduce and relieve excessive tension in your muscles (spasms) occurring in various illnesses such as cerebral palsy, multiple sclerosis, cerebrovascular accidents, spinal cord diseases and other nervous system disorders.

2. What you need to know before you take Baclopar

Do not take Baclopar:

- if you are allergic to baclofen or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor or pharmacist before taking Baclopar if you

- have porphyria (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders).
- have Parkinson's disease
- suffer from any mental health condition such as schizophrenia, psychosis, depressive or manic disorders or confusional states
- recently had a stroke or have reduced blood flow to the brain.
- have breathing difficulties or lung disease
- have a history of stomach or gut ulcers
- have a history of fits or suffer from epilepsy
- have a history of alcoholism, you drink alcohol to excess or you have a history of drug abuse or dependence
- have or being treated for high blood pressure
- have liver or kidney problems or have difficulty urinating (urinary retention)
- have diabetes
- have a child under one year of age since there is very limited information on the use of baclofen in this age group.

Some people being treated with baclofen have had thoughts of harming or killing themselves or have tried to kill themselves. Most of these people also had depression, had been using alcohol excessively or were prone to having thoughts of killing themselves. 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

Baclofen may be taken by children and adolescents 0 to 18 years of age. If your doctor considers that baclofen may be suitable for your child, Baclopar tablets should not be used in children under 33kg body weight. Other pharmaceutical formulations of baclofen may be more suitable.

Other medicines and Baclopar

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. In particular tell your doctor or pharmacist if you are taking any of the following:

- antidepressants such as lithium, clomipramine, imipramine, amitriptyline and any monoamine oxidase inhibitor (MAOI) e.g. phenelzine, moclobemide, selegiline
- medicine to lower blood pressure, e.g. captopril, amlodipine, diltiazem, propranolol, valsartan, furosemide, as your doctor may want to monitor your blood pressure
- medicines which may affect the kidney e.g. ibuprofen (usually for arthritis or pain relief)
- levodopa and carbidopa for Parkinson's disease
- insulin and/or oral hypoglycaemic agents (for diabetes)
- medicines which slow down the nervous system e.g. anti-histamines, opiate pain killers, sedatives and anti-convulsants

If any of the above applies to you, talk to your doctor or pharmacist before taking Baclopar.

Operations and tests

Your doctor may give you check-ups from time to time while you are beginning treatment with Baclopar, especially if you have diabetes or any liver problems.

If you need to have an operation and will be given a general anaesthetic tell the doctor or the hospital staff you are taking this medicine.

Elderly (ages 65 or above) or people with muscle spasms caused by a brain disease

You may experience more side effects. Therefore, your doctor will keep you under appropriate surveillance and may adjust the dose of Baclopar you take.

Baclopar with alcohol

You should not drink alcohol while taking Baclopar tablets, it may affect you more than usual and make you feel tired or sleepy.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Baclofen should be avoided in pregnancy, unless the benefit of treatment for the mother outweighs the risks to the unborn baby. If you have to take Baclopar during pregnancy your baby might have convulsions just after delivery.

Baclopar passes into mother's milk but in small amounts and no effects on your baby are expected. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive or operate machines if you feel drowsy, very sleepy or dizzy or your eyesight is affected while taking Baclopar tablets.

Baclopar contains lactose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Baclopar contains sodium. This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Baclopar

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will adjust your dose of Baclopar tablets so that it is the most appropriate for you.

Take Baclopar with meals and with a little liquid. If you feel sick after taking Baclopar you may find it helps to take it with food or a milk drink.

How much to take

Adults - The recommended starting dose is 15 mg a day, in 3 divided doses. The dose will slowly be increased until your symptoms are controlled. This may be between 30 mg to 80 mg a day, in 2 to 4 divided doses. Your doctor may decide to give you a higher dosage.

Elderly –may be more sensitive to the effects of baclofen, and will usually take a smaller daily dose, at the beginning of treatment, which may be gradually increased as required.

Use in children and adolescents (0 to 18 years) - treatment is adjusted according to their body weight. Children's treatment usually starts with very low dose (daily dose of approximately 0.3 mg for each kilogram of body weight), in 2 to 4 divided doses (preferably in 4 doses). The dosage is then gradually increased until it becomes sufficient for the child's individual requirements, this may be between 0.75 mg and 2 mg for each kilogram of body weight. Baclofen tablets are not suitable for use in children below 33 kg body weight. Other formulations of baclofen are available for children below 33 kg body weight.

If you have been treated for 6 weeks and you feel no improvement, tell your doctor. Your doctor will decide if you should continue taking Baclopar.

Patients with kidney problems - a recommended smaller daily dose of 5 mg baclofen a day is used. Your doctor will decide what the dose should be.

If you take more Baclopar than you should

Contact your doctor or nearest hospital casualty department at once. Take any remaining tablets and the container with you.

Signs of overdose are:

- feeling sick (nausea), being sick (vomiting) or diarrhoea
- feeling drowsy
- having a lower level or loss of consciousness
- difficulty in breathing
- trouble breathing during sleep (sleep apnoea)
- feeling confused or agitated or hallucinating
- unusual muscle weakness or sudden contraction of your muscle
- muscle pain
- excessive salivation
- fits (convulsions)
- fever and dark urine (rhabdomyolysis)
- abnormally low body temperature
- blurred vision
- ringing in the ears
- poor or absent reflexes
- high or low blood pressure
- slow, fast or irregular heartbeat.

If you have **kidney disease** and have accidentally taken more tablets than your doctor has prescribed, you may experience neurological symptoms of overdose (e.g. drowsiness, feeling confused, hallucinations).

If you forget to take Baclopar

If you forget to take a dose take it as soon as you remember. Do not take a double dose to make up for a forgotten tablet. If it is almost time for your next dose though, do not double the dose just carry on as before.

If you stop taking Baclopar

Do not stop taking Baclopar tablets suddenly - you may suffer from unpleasant withdrawal symptoms such as worsening of spasticity, increased muscle rigidity, muscle pain, fever and dark urine, hallucinations, changed mood and emotion, mental disorders, confusion, convulsions (fits), high body temperature or raised heart rate. If you need to stop treatment, your doctor will normally reduce the dose over 1 – 2 weeks.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects mainly occur at the start of treatment and are often mild. They normally wear off after a short period of time or improve by reducing the dosage.

If you notice any of the following serious side effects, contact your doctor straight away or go to the nearest hospital emergency department:

Common (may affect up to 1 in 10 people):

- Difficulty breathing, such as very slow or shallow breathing.
- Weakness, swelling in the legs and tiredness especially when exercising (decreased cardiac output)
- Loss of coordination affecting balance and walking, limb and eye movement or speech (signs of ataxia)
- Trembling
- Feeling extremely happy or depressed, confusion, hallucinations or nightmares
- Problems with eyesight
- Low blood pressure (fainting)
- Skin rash
- Problems in passing urine, including increased need to pass urine, loss of control or pain on passing urine

Rare (may affect up to 1 in 1,000 people):

- Convulsions (especially in patients with epilepsy)
- Decreased need to pass urine
- Liver problems, abdominal pain and yellowing of the skin or eyes

Not known (frequency cannot be estimated from the available data)

- Slow Heartbeat
- Hives
- Symptoms such as anxiety, confusion, hallucinations, fast heartbeat which occur after suddenly stopping treatment (Drug withdrawal)

If you experience any of the above serious side effects, stop taking Baclopar, you may need immediate medical attention.

Other possible side effects:

Very common (may affect more than 1 in 10 people):

- Drowsiness or sleepiness
- Nausea (feeling sick)

Common (may affect up to 1 in 10 people):

- Headache, dizziness or light-headedness
- Tiredness and exhaustion
- Sleeplessness (insomnia)
- Dry mouth
- Weakness or pain in your muscles
- Stomach problems including retching, being sick, constipation and diarrhoea
- Excessive sweating

Rare (may affect up to 1 in 1,000 people):

- Numbness or tingling in hands or feet
- Disturbed sense of taste
- Slurred or slow speech
- Sexual problems in men, e.g. impotence

Very Rare (may affect up to 1 in 10,000 people)

- hypothermia

Not known (frequency cannot be estimated from the available data):

- Increase in blood sugar, which will show up in tests, you may notice increased hunger, feeling thirsty or needing to pass water more often
- Trouble breathing during sleep (sleep apnoea syndrome)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Baclopar tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date, which is stated on the label. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Baclopar contains

- The active substance is baclofen
- One tablet contains 10 mg baclofen
- The other ingredients are lactose monohydrate (see section 2 “Baclopar contains lactose”), cellulose microcrystalline, calcium hydrogen phosphate anhydrous, sodium starch glycolate (Type A), silica colloidal anhydrous and magnesium stearate.

What Baclopar looks like and contents of the pack

Baclopar 10 mg tablets are white, flat bevel-edged tablets marked “BN” breakline “10” on one side and “G” logo on the reverse.

Baclopar is available in HDPE bottles of 50 or 100 tablets, or in blister pack of 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Viatrix Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland

Manufacturer

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Laboratories SAS – Chatillon Sur Chalaronne, route de Belleville, lieu-dit Maillard, Chatillon Sur Chalaronne, 01400, France.

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