

PART III: CONSUMER INFORMATION

Pr
MYLAN-BACLOFEN
Baclofen Tablets
10 mg and 20 mg

This leaflet is part III of a three-part "Product Monograph" published when MYLAN-BACLOFEN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MYLAN-BACLOFEN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

MYLAN-BACLOFEN is one of a group of medicines called muscle relaxants.

MYLAN-BACLOFEN is used to reduce and relieve the excessive stiffness and/or spasms in your muscles occurring in various conditions such as multiple sclerosis and diseases or injuries of the spinal cord.

What it does:

Due to the relaxation of muscle and the consequent relief from pain, MYLAN-BACLOFEN improves your ability to move, makes it easier for you to manage your daily activities and facilitates physiotherapy.

If you have any questions about how MYLAN-BACLOFEN works or why this medicine has been prescribed for you, ask your doctor.

When it should not be used:

Do not take MYLAN-BACLOFEN:

- If you are allergic (hypersensitive) to baclofen or any of the other ingredients listed in **"What the nonmedicinal ingredients are"**.

If this applies to you, tell your doctor without taking MYLAN-BACLOFEN.

If you think you may be allergic, ask your doctor for advice.

What the medicinal ingredient is:

The active substance of MYLAN-BACLOFEN is baclofen.

What the non-medicinal ingredients are:

The non-medicinal ingredients are: anhydrous Lactose, microcrystalline cellulose, dibasic calcium phosphate, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate.

What dosage forms it comes in:

MYLAN-BACLOFEN is available in 10 mg and 20 mg tablets.

WARNINGS AND PRECAUTIONS

SERIOUS WARNINGS AND PRECAUTIONS

Taking MYLAN-BACLOFEN with opioid medicines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

BEFORE you use MYLAN-BACLOFEN talk to your doctor or pharmacist if you:

- Have kidney disease. Your doctor will decide whether or not MYLAN-BACLOFEN is the appropriate treatment for you;
- Are suffering from epilepsy (seizures);
- Have acute pain in your stomach (ulcer) or intestines, breathing problems, liver disease, or a disturbance of blood circulation in your brain;
- Are taking medicines for arthritis or pain (see section: **"Interactions with this medication"**);
- Have difficulty urinating;
- Have Parkinson's disease or certain mental illnesses accompanied by confusion or depression;
- Are diabetic;
- Have or had thoughts of harming or killing yourself, have or had depression, have a history of alcoholism or drink alcohol to excess, have a history of drug abuse and dependence, or are

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taking medicines associated with increased suicide risk;

- 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 behavior and ask them to read this leaflet.

Older people (aged 65 years or above) or people with a disturbance of circulation in the brain

If you are in one of these groups, you may experience more side effects. Therefore, your doctor will keep you under appropriate surveillance and may adapt the dose of MYLAN-BACLOFEN you take.

Children and adolescents

Safe use of MYLAN-BACLOFEN in children under age 12 has not been established and it is therefore not recommended for use in children.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

You should not use MYLAN-BACLOFEN during pregnancy unless your doctor advises you to do so. Tell your doctor if you are pregnant, planning to become pregnant, or breast-feeding. He or she will discuss with you the potential risk of taking MYLAN-BACLOFEN during pregnancy or if you are breast-feeding. Use of MYLAN-BACLOFEN during pregnancy may result in the newborn experiencing withdrawal from the drug including, irritability, high-pitched crying, trembling, increased muscle tone, excessive sucking, disordered sleep, increase in body temperature, uneven discolored patches on the skin, and convulsions and other symptoms related to sudden stop of treatment sometime after delivery. Your doctor may need to treat your newborn for withdrawal reactions.

Driving and using machines

In some people, MYLAN-BACLOFEN may be associated with dizziness, sleepiness or visual disturbance. If this happens to you, do not drive a car,

use a machine, or do other things that need your full attention.

Further safety measures

Before having any kind of surgery (including by the dentist), or emergency treatment, tell the doctor in charge that you are taking MYLAN-BACLOFEN.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with MYLAN-BACLOFEN include:

- Alcohol;
- Sedative drugs;
- Medicines used to treat mood disorders such as antidepressants and lithium;
- Medicines used to treat high blood pressure;
- Medicines used to treat Parkinson's disease;
- Medicines for arthritis or pain.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You should not drink alcohol during your treatment with MYLAN-BACLOFEN.

PROPER USE OF THIS MEDICATION

Usual dose:

Follow your doctor's instructions carefully. Do not exceed the recommended dose.

How much MYLAN-BACLOFEN to take

Treatment usually starts with 15 mg daily, preferably taken in divided doses. The dose is then gradually increased until the best results are obtained; this may be between 40 mg to 80 mg per day, taken in divided doses.

The dose prescribed by your doctor may be different from that written here. If this is the case, follow the doctor's instructions.

Your doctor will tell you exactly how many tablets of MYLAN-BACLOFEN to take.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

When to take MYLAN-BACLOFEN

Taking MYLAN-BACLOFEN at the same time each day will help you to remember when to take your medicine.

How to take MYLAN-BACLOFEN

Be sure to take this medicine regularly, and exactly as your doctor tells you. This will help you to get the best results and reduce the risk of side effects.

How long to take MYLAN-BACLOFEN

Continue taking MYLAN-BACLOFEN as your doctor tells you.

If you have questions about how long to take MYLAN-BACLOFEN talk to your doctor or your pharmacist.

Do not suddenly stop taking MYLAN-BACLOFEN without first checking with your doctor. He or she will tell you when and how you can stop taking this medicine; stopping suddenly can make your condition worse.

If you stop your treatment suddenly, you may experience: nervousness, feeling confused, hallucinations, abnormal thinking or behaviour, convulsions, uncontrollable twitching, jerking or writhing movements, fast heart beat, high body temperature. The excessive stiffness (spasms) in your muscles may also worsen.

Overdose:

If you have accidentally taken many more tablets than your doctor has prescribed, seek immediate emergency medical treatment, even though you do not feel sick.

The main symptoms of overdose are drowsiness, breathing difficulties, trouble of consciousness and being unconscious (coma).

Other symptoms may include: feeling confused, hallucinations, agitation, convulsions, blurred vision, unusual muscle weakness, sudden contraction of the muscles, poor or absent reflexes, high or low blood pressure, slow, fast or irregular heart beat, low body temperature, nausea, vomiting, diarrhea or excessive salivation, trouble breathing during sleep (sleep apnoea), pain in muscles, fever and dark urine (rhabdomyolysis).

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

Missed Dose:

If you have forgotten to take one of your scheduled doses, take it as soon as you remember. However, if it is almost time for your next dose, do not take the missed one at the same time as the scheduled one, otherwise you will be doubling the dose. Just go back to your regular dosing timetable. If you have forgotten to take several doses you should contact your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, MYLAN-BACLOFEN can have some side effects, although not everybody gets them. These are often mild and are usually at the start of treatment; they normally wear off after a few days.

Very common side effects

These side effects may affect more than 1 in 10 patients:

- Drowsiness, sleepiness;
- Nausea.

If any of these affects you severely, **tell your doctor.**

Common side effects

These side effects may affect between 1 and 10 in every 100 patients:

- Feeling faint, tiredness, dizziness, headache, inability to sleep, weakness in arms and legs, pain in muscles, uncontrollable eye movements, dry mouth;

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- Disturbance of the digestive tract, retching, vomiting, constipation, diarrhea;
- Sweating a lot;
- Passing more urine than normal, bedwetting.

If any of these affects you severely, **tell your doctor.**

Rare side effects

These side effects may affect between 1 and 10 in every 10,000 patients:

- Tingling or numbness of the hands and/or feet, difficulty in speaking, taste disturbance;
- Abdominal pain;
- Sudden decrease in urine;
- Inability to get or to maintain an erection (impotence).

Side effect also reported (frequency unknown)

- Increased blood sugar;
- Drug misuse, drug abuse, drug dependence.

If any of these affects you severely, **tell your doctor.**

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical treatment
		Only if severe	In all cases	
Common	Breathing problems		√	
	Feeling of confusion		√	
	Feeling of extreme happiness		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
	Sad mood (depression)		√	
	Loss of coordination affecting balance and walking, limb and eye movements and/or speech (signs of ataxia)		√	
	Trembling		√	
	Hallucinations		√	
	Nightmares		√	
	Blurred vision/visual disturbance		√	
	Shortness of breath at rest or with activity, swelling in the legs and tiredness (signs of decreased cardiac output)		√	
	Low blood pressure (hypotension)		√	
	Skin rash and hives		√	
	Difficulty passing urine, pain when passing urine or a sudden decrease in urine.		√	

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SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Rare	Abdominal pain, yellowing of the skin or eyes and tiredness (signs of liver disturbance)			√
	Convulsions			√
Very Rare	Low body temperature		√	
Not Known	Symptoms following sudden discontinuation of the medicine (drug withdrawal syndrome)		√	
	Slow heart beat		√	
	Suicidal Behavior: thoughts or actions about harming or killing yourself		√	

This is not a complete list of side effects. For any unexpected effects while taking MYLAN-BACLOFEN, contact your doctor or pharmacist.

HOW TO STORE IT

- Store at room temperature between 15°C and 30°C.
- Do not use after the expiry date shown on the bottle.
- Protect from heat and humidity.
- Keep out of the reach and sight of children.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

If you want more information about MYLAN-BACLOFEN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>) or by calling 1-844-596-9526

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