

Baclofen (Noumed)

Baclofen Ph.Eur.

10 mg uncoated tablets

What is in this leaflet

Please read this leaflet carefully before you start using Baclofen (Noumed).

This leaflet answers some common questions about Baclofen (Noumed). It does not contain all the available information. It 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 you using Baclofen (Noumed) against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Baclofen (Noumed) is used for

Baclofen (Noumed) is used to reduce excess tension in your muscles which causes spasms. These spasms happen in various illnesses such as multiple sclerosis and diseases or injuries of the spinal cord.

Because this medicine reduces spasms and the pain that goes with them, it helps to make you more mobile. This can help you to manage your daily activities more easily.

Baclofen (Noumed) contains the active ingredient baclofen. It belongs to a group of medicines called muscle relaxants.

It works by reducing the excessive stiffness and/or spasms in your muscles.

Your doctor may have prescribed Baclofen (Noumed) for another reason.

Ask your doctor if you have any questions about why Baclofen (Noumed) has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use Baclofen (Noumed)

When you must not use it

Do not use Baclofen (Noumed) if you have an allergy to:

- any medicine containing baclofen
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin.

Do not take Baclofen (Noumed) if you have peptic ulceration, a condition where there are painful sores or ulcers in the lining of the stomach and/or small intestines.

Do not give Baclofen (Noumed) to children weighing less than 33 kg.

Baclofen (Noumed) should be used with extreme caution in children under 16 years old but weighing more than 33 kg.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it is expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using Baclofen (Noumed), talk to your doctor.

Before you start to use it

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

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you have or have had any of the following medical conditions:

- a mental illness
- epilepsy or any other condition that causes convulsions, fits or seizures
- stomach or duodenal ulcers
- stroke or other brain blood vessel disease
- kidney disease
- liver disease
- lung problems which make breathing difficult

- diabetes
- alcoholism
- high blood pressure
- Parkinson's disease
- muscle spasms due to stroke or other brain disease
- porphyria, an uncommon genetic condition.

Your doctor may want to take special precautions if you have any of the above conditions.

If you have not told your doctor about any of the above, tell him/her before you start using Baclofen (Noumed).

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking Baclofen (Noumed).

Some medicines may interfere with Baclofen (Noumed). These include:

- medicines that can cause sedation (make you sleepy) such as some pain relievers; medicines for anxiety, travel sickness, hayfever or allergy, cough and cold, blocked nose; muscle relaxants; sleeping tablets or sedatives
- medicines used to treat depression, including tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs)
- lithium, a medicine used to treat mood swings and some types of depression
- insulin and medicines used to treat diabetes
- medicines for high blood pressure
- levodopa alone or with carbidopa combination medicines used to treat Parkinson's disease.

These medicines may be affected by Baclofen (Noumed) or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

If you are not sure if you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Baclofen (Noumed).

How to use Baclofen (Noumed)

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the carton, ask your doctor or pharmacist for help.

How much to take

Treatment is usually started with small doses of Baclofen (Noumed). The dose is then gradually increased to an amount that works best for you.

For example, Baclofen (Noumed) may be started at a dose of 15 mg a day, then increased slowly to anywhere from 30 to 80 mg a day. Sometimes doses up to 120 mg a day may be needed.

If you are under the age of 16 or over 65 or you have kidney disease, your doctor may start you on a lower dose and increase it more gradually to prevent unwanted side effects.

The tablets can be halved if required.

How to take it

Swallow the tablets during meals with a glass of water or other liquid.

Baclofen (Noumed) is usually taken in 3 – 4 divided doses throughout the day. But your doctor may tell you to take it more or less often, depending on your situation.

The tablets can be halved if required.

When to take it

Take your medicine at about the same time(s) each day.

Taking it at the same time(s) each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you are well.

Continue taking the medicine until you finish the pack.

If you forget to take it

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

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are using Baclofen (Noumed)

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Baclofen (Noumed).

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

If your muscle spasms come back, tell your doctor.

Your doctor may be able to change the dose of Baclofen (Noumed) so it works better for you.

Things you must not do

Do not stop taking Baclofen (Noumed) suddenly or change the dose without checking with your doctor.

Do not let yourself run out of your medicine over weekends or during holidays. Stopping Baclofen (Noumed) suddenly may cause unwanted effects such as mood changes or mental disturbances, seizures (fits), a fast heartbeat and worsening muscle spasms. If Baclofen (Noumed) must be stopped, your doctor will reduce the dose gradually over a period of 1 to 2 weeks so that these unwanted effects are avoided.

Do not take Baclofen (Noumed) to treat any other complaints unless your doctor tells you to.

Do not give Baclofen (Noumed) to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Baclofen (Noumed) affects you.

This medicine may cause dizziness, light-headedness, tiredness, and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, drowsiness may be worse. Your doctor may suggest you avoid alcohol while you are taking Baclofen (Noumed).

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Baclofen (Noumed). Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include drowsiness, decreased ability to inhale/exhale, and reduced levels or loss of consciousness.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Baclofen (Noumed).

This medicine helps most people with muscle spasms, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Side effects from Baclofen (Noumed) happen mainly at the start of treatment or if the dose is too high or is increased too rapidly. They can often be relieved by lowering the dose.

If you are over 65 years of age, you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- sleepiness or drowsiness
- lack of energy, feeling exhausted
- dizziness or light-headedness, spinning sensation (vertigo)
- headache
- difficulty sleeping or nightmares
- nausea (feeling sick), retching or vomiting
- constipation, stomach cramps or diarrhoea
- loss of appetite
- dry mouth
- change in sense of taste
- excessive sweating
- impotence or inability to ejaculate
- misuse, abuse and dependence
- suicide or suicide attempts.

The above list includes the more common side effects of your medicine. They are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- mental confusion, depression or hallucinations (seeing or hearing things that are not there)
- numbness or tingling in hands and feet
- muscle weakness, spasms or pain
- problems with coordination and balance
- blurred or double vision
- ringing in the ears
- frequent urination or bed wetting
- difficulty or pain when urinating
- blood in the urine
- swelling of ankles due to fluid build-up
- low body temperature

- difficulty in speaking.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath or wheezing
- slow or difficult breathing
- slow/fast or irregular heartbeat
- chest pain
- uncontrollable muscle spasms affecting the eyes, head, neck or body
- fainting or seizures (fits)

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Some other side effects (for example, changes in liver function, blood pressure or blood sugar levels) can only be found when your doctor does tests from time to time to check your progress.

After using Baclofen (Noumed)

Storage

Keep your tablets in the blister strip until it is time to take them.

If you take the tablets out of the blister, they may not keep well.

Keep your tablets in a cool, dry place where the temperature stays below 25 °C.

Do not store Baclofen (Noumed) or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Protect from moisture.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Baclofen (Noumed) are white-coloured, round-shaped, flat tablets, debossed with 'B' and '10' separated by break line on one side and plain on the other side.

Ingredients

Active ingredient:

Each Baclofen (Noumed) contains 10 mg of baclofen as the active ingredient.

Inactive ingredients:

Baclofen (Noumed) tablets also contain the following inactive ingredients:

Colloidal silicon dioxide
Magnesium stearate
Maize starch
Microcrystalline cellulose
Povidone

Sponsor Details

Baclofen (Noumed) is supplied in New Zealand by:

Noumed Pharmaceuticals Limited

Level 2, Fidelity House, 81 Carlton Gore Road,
Newmarket, Auckland 1023
NEW ZEALAND

Freephone 0800 527545

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