

PACIFEN

Baclofen 10mg Tablets



What is in this leaflet

This leaflet answers some common questions about PACIFEN. It does not contain all the information available on this medicine. 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 taking PACIFEN 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. You may want to read it again.

What PACIFEN is used for

PACIFEN belongs to a group of medicines called muscle relaxants.

This medicine 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.

Ask your doctor if you have any questions about why PACIFEN has been prescribed for you. Your doctor may have prescribed it for another purpose.

PACIFEN is only available with a doctor's prescription.

Before you take PACIFEN

When you must not take it

Do not take PACIFEN if you have ever had an allergic reaction after taking:

- baclofen (the active ingredient in PACIFEN)
- any of the other 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 PACIFEN after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If you take this medicine after the expiry date, it may not work as well.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are pregnant or intend to become pregnant or you are breast-feeding. There is very little information on the use of this medicine in pregnancy or while breast-feeding. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you have, or have ever 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
- heart disease
- kidney disease
- liver disease
- lung problems which make breathing difficult
- diabetes
- alcoholism
- high blood pressure
- Parkinson's disease
- if you have a disease known as 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 these things, tell them before you start taking PACIFEN.

Taking other medicines

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

Some medicines may be affected by PACIFEN, or may affect how well it works. These include:

- medicines that can cause sedation (makes you sleepy) such as some pain relievers; medicines for anxiety, travel sickness, hay fever or allergy, cough and cold, blocked nose; 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 depressions
- insulin and medicines used to treat diabetes
- medicines for high blood pressure
- levodopa and carbidopa combinations, medicines used to treat Parkinson's disease.

You may need to take different amounts of your medicines or you may need to take different medicines.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking PACIFEN.

How to take PACIFEN properly

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

These directions may differ from the information contained in this leaflet.

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

How much to take

Treatment is usually started in hospital with small doses of PACIFEN.

The dose is then gradually increased to an amount that works best for you.

For example, PACIFEN may be started at a dose of 15 mg a day, then increased slowly to anywhere from 30 to 75 mg a day. Sometimes, doses up to 100 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.

How to take it

Swallow the tablets during meals with water or other liquid.

PACIFEN is usually taken in at least 3 divided doses throughout the day. But your doctor may tell you to take it more or less often, depending on your situation.

If you forget to take it

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

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

Do not take a double dose to make up for the one that 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 when to take your medicine, ask your pharmacist for some hints.

How long to take it

Continue taking PACIFEN for as long as your doctor recommends.

Your doctor will check your progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

While you are taking PACIFEN

Things you must do

If you become pregnant while taking PACIFEN, tell your doctor immediately. Your doctor can discuss with you the risks of taking it while you are pregnant.

Be sure to keep all of your doctor's appointments so that your progress can be checked. To help prevent unwanted side effects from happening, your doctor may want to do some tests from time to time during the course of your treatment.

If your muscle spasms come back, tell your doctor. Your doctor may be able to change the dose of PACIFEN to make it work better for you.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking PACIFEN.

Tell any other doctor, dentist or pharmacist who treats you that you are taking PACIFEN.

If you plan to have surgery that requires a general anaesthetic, including dental surgery, tell your doctor or dentist that you are taking PACIFEN.

Things you must not do

Do not stop taking PACIFEN 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 PACIFEN suddenly may cause unwanted effects such as mood changes or mental disturbances, seizures (fits), a fast heart beat and worsening of muscle spasms. If PACIFEN 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 use PACIFEN to treat any other complaints unless your doctor tells you to.

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

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking PACIFEN until you know how it affects you. This medicine may cause sleepiness and decreased alertness in some people, especially at the start of treatment.

Be careful when drinking alcohol while you are taking PACIFEN. The combination may make you feel more sleepy and less alert than usual. Your doctor may suggest you avoid alcohol while you are taking PACIFEN.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PACIFEN.

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 side effects.

Side effects 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 old, you should be especially careful while taking this medicine. Report any side effects promptly to your doctor.

As people grow older, they are more likely to get side effects from medicines.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

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

- sleepiness or drowsiness
- lack of energy, feeling exhausted
- dizziness or lightheadedness, 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.

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 buildup.

The above list includes serious side effects which 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
- fast or irregular heart beat
- 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.

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

This is not a complete list of all possible side effects. Other side effects not listed above may happen in some people.

Storage conditions

Storage

- Keep your tablets in the original container until it is time to take them
- Store the tablets in a cool dry place
- Do not take this medicine after the expiry date shown on the bottle or if the packaging shows signs of tampering.
- Do not store PACIFEN or any other medicine in the bathroom or near a sink
- Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines. PACIFEN will keep well if it is cool and dry.

Keep the tablets where young children cannot reach them.

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

Disposal

If your doctor tells you to stop taking PACIFEN or the expiry date on the medicine has passed, ask your pharmacist what to do with any tablets you have left over.

In case of overdose

You should only take the number of tablets that you have been told. Some of the symptoms of an overdose may include drowsiness, confusion, unusual muscle weakness, blurred vision, vomiting, diarrhoea, excessive saliva, breathing problems, slow heartbeat, fainting or seizures (fits).

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any PACIFEN by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of PACIFEN with you if you can.

Keep telephone numbers for these places handy.

Product description

What PACIFEN tablets look like

PACIFEN 10 mg tablets are white, round, flat bevelled edged marked BN | 10 on one side and G on the other. Each tablet contains 10mg of baclofen and has a diameter of 7mm.

Ingredients

Each PACIFEN 10mg tablet contains 10mg of the active ingredient, baclofen.

Other ingredients

- Microcrystalline Cellulose
- Lactose
- Calcium Hydrogen Phosphate
- Colloidal Silicon Dioxide
- Sodium Starch Glycollate
- Magnesium Stearate

PACIFEN tablets are gluten free.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone (09) 579 2792

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