

APO-Baclofen Tablets

Contains the active ingredient baclofen

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about baclofen. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO- Baclofen Tablets. It contains the active ingredient baclofen.

It is used to treat:

- multiple sclerosis
- spinal cord damage resulting from disease or physical injury.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

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

How it works

Baclofen belongs to a group of medicines called muscle relaxants.

It is used to reduce excess tension in your muscles which causes spasms. Because this medicine reduces spasms and the pain that goes with them, it helps to make you more mobile. This helps you to manage your daily activities more easily.

There is no evidence that this medicine is addictive.

Use in children

Baclofen should be used with extreme caution in children under 16 years of age as only limited information is available. Baclofen should not be used in children who weigh less than 33 kg.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, baclofen or any of the ingredients listed at the end of this leaflet.** Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of

the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - lactose intolerance. This medicine contains a small amount of lactose.
 - a psychiatric illness
 - Parkinson's disease
 - seizures (fits) from any cause
 - stiffness and restriction of movement in muscle groups
 - stomach or duodenal ulcers
 - stroke or other blood vessel disease
 - heart problems
 - kidney problems
 - liver problems
 - breathing problems or lung problems which make breathing difficult
 - problems with urination
 - diabetes
 - high blood pressure
 - porphyria, a disorder which can affect the liver and blood formation
 - alcohol dependence.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with baclofen.

These include:

- any medicine that tends to make you sleepy, such as medicines used to help you sleep, calm down (e.g. diazepam), relax muscles (e.g. tizanidine), pain relievers (e.g. morphine), travel sickness medicines and medicines for colds or allergies. These may

add to the sedative effect of baclofen. Alcohol will also have this effect.

- some medicines used for depression, such as tricyclic antidepressants, lithium and monoamine oxidase inhibitors (MAOIs)
- medicines for high blood pressure
- medicines used to treat Parkinson's disease, including levodopa and carbidopa
- medicines used to treat diabetes
- medicines which may affect the way your kidney works.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with baclofen.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

You would normally start by taking small doses of baclofen in hospital.

The dose is then gradually increased to an amount that works best for you. For example, baclofen 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 side effects.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablets with some water.

When to take it

Take the tablets during meals.

This will lessen the chance of a stomach upset. Baclofen is usually taken in at least three divided doses throughout the day. But your doctor may tell you to take it more or less often, depending on your situation.

Take this medicine at the same time each day.

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

How long to take it for

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

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

Do not stop taking baclofen suddenly.

This medicine is not habit-forming, but stopping it suddenly may bring on severe spasms and other side effects.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much baclofen you may feel drowsy, have problems breathing or lose consciousness.

You may also feel confused, hallucinate (imagine things that are not there), have unusual muscle weakness, blurred vision, feel sick (nausea), be sick (vomit), faint, have diarrhoea, increased saliva, slow or irregular heartbeat, or fits (seizures).

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

This medicine is not habit-forming, but stopping it suddenly may bring on severe spasms and other side effects.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

This medicine may cause sleepiness, dizziness, lightheadedness and decreased alertness in some people, especially at the start of treatment.

Be careful when drinking alcohol while you are taking baclofen.

The combination may make you feel more sleepy, dizzy or lightheaded and less alert than usual.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking baclofen or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- daytime 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
- stuffy or blocked nose
- dry mouth
- change in sense of taste
- mild rash or mildly itchy skin
- ringing in the ears
- frequent urination or bed wetting
- excessive sweating
- erection problems or inability to ejaculate
- weight gain.

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

These may be serious side effects and you may need medical attention:

- mental confusion
- numbness or tingling in hands and feet
- muscle weakness, spasms or pain
- swelling of ankles due to fluid build-up
- blurred or double vision
- problems with coordination, balance and movement
- difficulty in speaking
- increased blood sugar
- low body temperature.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- slow or difficult breathing
- fast or irregular heart beat
- fainting or loss of consciousness
- seizures (fits)
- chest pain
- uncontrollable muscle spasms affecting the eyes, head, neck or body
- depression or other severe mood or mental changes
- hallucinations (feeling, hearing or seeing things that are not there)
- being unable to urinate or pain when urinating; blood in the urine
- symptoms following discontinuation of the medicine (such as spasms).

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to baclofen, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Baclofen looks like

Baclofen 10 mg tablets:

White, oval, flat-faced, bevel-edged tablets scored and engraved "APOB10" on one side.

Baclofen 25 mg tablets:

White, round, flat-faced, bevel-edged tablets, scored on one side.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 10 mg or 25 mg of baclofen as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- maize starch
- microcrystalline cellulose
- magnesium stearate.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Baclofen 10 mg tablets, 100 Tablets per bottle:
AUST R 77577

APO- Baclofen 25 mg tablets, 100 Tablets per bottle:
AUST R 77576

Sponsor

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