

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

This leaflet answers some common questions about this medicine. 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 taking this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need 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

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.

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

Your doctor may have prescribed it for another reason.

There is no evidence that this medicine is addictive.

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

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 have an allergy to:

- baclofen
- 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.

Do not take this medicine if you are currently pregnant or you plan to become pregnant.

Do not take this medicine until you and your doctor have discussed the risks and benefits involved.

If you must take baclofen during pregnancy, your baby may have convulsions and other symptoms related to sudden discontinuation of the medicine just after delivery.

Do not take this medicine if you are currently breastfeeding or you plan to breastfeed.

Baclofen may pass into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine until you and your doctor have discussed the risks and benefits involved.

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

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 have allergies to any other medicines, foods, preservatives or dyes.

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

- lactose intolerance – this medicine contains a small amount of lactose
- any mental/psychiatric illness
- Parkinson's disease
- seizures (fits) from any cause
- stiffness and restriction of movement in a group of muscles
- stomach or duodenal ulcers
- stroke or other blood vessel diseases
- heart problems
- kidney problems
- liver problems
- lung problems which make breathing difficult
- diabetes
- high blood pressure
- porphyria, a disorder which can affect liver function and blood formation
- alcohol dependence

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.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription 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 or calm you 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
- medicines used to treat mood disorders such as tricyclic antidepressants, lithium and monoamine oxidase inhibitors (MAOIs)
- medicines used to treat 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

These medicines may be affected by baclofen or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take this medicine

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 label, ask your doctor or pharmacist for help.

How much to take

This will depend on your condition and whether you are taking any other medicines.

Treatment is normally started in hospital with small doses of baclofen.

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.

How to take it

Swallow the tablets during meals with some water.

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.

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.

If you forget to take it

If it is almost time to take 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 missed doses.

This may increase the chance of you experiencing side effects.

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 to help you remember.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and

Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose include feeling drowsy, having problems breathing or losing 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).

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)

While you are taking this medicine

Things you must do

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

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 or start to breastfeed 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 occasionally do tests to make sure the medicine is working and to prevent side effects.

Go to your doctor regularly for a check-up.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without 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, operating machinery or doing jobs that require you to be alert until you know how this medicine affects you.

Baclofen may cause sleepiness, dizziness, light-headedness 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.

Side effects

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

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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 if you notice any of the following and they worry you:

- daytime sleepiness or drowsiness
- lack of energy or 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:

- 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.

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

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

- 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 sudden discontinuation of the medicine (such as spasms).

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

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

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 stays below 25°C.

Do not store this 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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. AUST R 77577.

Baclofen 25 mg tablets:

White, round, flat-faced, bevel-edged tablets, scored on one side. AUST R 77576.

Bottle packs of 100 tablets.

* 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 monohydrate
- maize starch
- microcrystalline cellulose
- magnesium stearate.

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

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

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