

Gabapentin APOTEX Capsules

Contains the active ingredient gabapentin

Consumer Medicine Information

WARNING: Before taking Gabapentin, tell your doctor if you have a history of drug abuse. Gabapentin poses risks of abuse and dependence. Using Gabapentin with other medicines that can make you feel drowsy such as sleeping tablets and other pain relievers (e.g., benzodiazepines and opioids), antihistamines, antidepressants, antipsychotics, cannabis, and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. If you have any concern about taking this medicine, speak to your doctor.

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about gabapentin. 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 Gabapentin APOTEX capsules. It contains the active ingredient, gabapentin.

- control epilepsy, a condition that causes repeated seizures (fits). There are many different types of seizures, ranging from mild to severe
- treat neuropathic pain (pain due to nerves being damaged or affected).

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

Gabapentin belongs to a group of medicines called anticonvulsants.

It is thought to work by controlling brain chemicals which send signals to nerves to help control seizures or neuropathic pain.

This medicine helps to relieve pain.

Your doctor may prescribe gabapentin in addition to your current treatment when your current treatment is no longer working as well.

Your doctor may have prescribed Gabapentin for another reason.

Gabapentin may lead to dependence on this medicine.

Ask your doctor if you have any question about why Gabapentin has prescribed for you.

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

Use in children

There is not enough information the use of this medicine in children under the age of:

- 3 years to control epilepsy
- 18 years for the treatment of neuropathic pain.

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 gabapentin or any of the ingredients listed at the end of this leaflet. 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.
- 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.
- If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking Gabapentin, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines, especially barbiturates or any other anticonvulsant medicine.
- any other substances, such as foods, preservatives or dyes.

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

- kidney problems
- mixed seizure disorders that include absence seizure

Tell your doctor if you have a history of drug abuse.

Gabapentin poses risks of abuse and dependence. Your body may become used to you taking Gabapentin and this may result in physical dependence. It means that you may experience withdrawal symptoms if you stop taking Gabapentin suddenly. So it is important to strictly follow the directions given by your doctor.

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

Gabapentin may affect your developing baby if you take it during pregnancy. However, it is very important to control your fits while you are pregnant. If it is necessary for you to take this medicine your doctor can help you

decide whether or not to take it during pregnancy.

Tell your doctor if you are breastfeeding or plan to breast-feed.

Gabapentin passes into breast milk. The effect on your breast-fed baby is unknown.

If you do breast-feed, watch your baby carefully.

If your baby develops a skin rash, becomes sleepy or has unusual symptoms, don't breast-feed again until you speak to your doctor.

Your doctor can discuss the risks and benefits of breast-feeding with you.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Gabapentin.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by Gabapentin 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 or pharmacist will advise you accordingly.

Gabapentin and certain other medicines may influence each other.

Using Gabapentin with other medicines that can make you feel drowsy, such as sleeping tablets and other pain relievers (e.g., benzodiazepines and opioids), antihistamines, antidepressants, antipsychotics, cannabis, and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death.

Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation.

Tell your doctor or pharmacist if you are taking any of the following:

- cimetidine, a medicine used to treat stomach or duodenal ulcers, or reflux
- antacids, medicines used to treat heartburn or reflux.
- opioids, medicines used to treat severe pain e.g. morphine.

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

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.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

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

Your doctor may recommend that you start with a low dose of gabapentin and then slowly increase the dose to the lowest amount needed to control your epilepsy or neuropathic pain.

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

How to take it

Swallow gabapentin capsules with a full glass of water.

When to take it

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. If you are taking gabapentin three times a day, do not allow more than 12 hours between doses.

It does not matter if you take it before, with or after food.

If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of this medicine.

How long to take it for

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

This medicine helps control your condition but does not cure it. Therefore, you must take it every day, even if you feel well.

Do not stop taking Gabapentin, or lower the dose, without checking with your doctor.

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

Stopping Gabapentin suddenly may worsen your condition or increase your chances of experiencing withdrawal symptoms, such as sleeplessness, headache, nausea (feeling sick), anxiety, excessive sweating or diarrhoea (runny stools). If appropriate, your doctor will slowly reduce your dose before you can stop taking it completely.

If you forget to take it

If it is almost time for your next dose (within 4 hours), 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)

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 gabapentin, you falling unconscious, feeling drowsy, weak, and unsteady when walking, have double vision, slurred speech or diarrhoea.

While you are taking this medicine

Things you must do

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

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

If you are going to have surgery or emergency treatment, tell the surgeon or anaesthetist that you are taking Gabapentin.

Tell your doctor immediately if you have any thoughts of suicide or self-harm, any unusual changes in mood or behaviour, or show signs of depression.

Some people being treated with antiepileptic, such as Gabapentin, have thoughts of harming or killing themselves.

Patients and caregivers should be alert and monitor for signs and symptoms of suicide, these includes:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- new or an increase in aggressive behaviour, irritability or agitation
- new onset of or worsening of depression.

Mention of suicide or violence must be taken seriously.

If you or someone you know is demonstrating these warnings signs and symptoms of suicide while taking Gabapentin, contact your doctor or a mental health professional right away.

Tell your doctor if you feel Gabapentin is not helping your condition.

Your doctor may need your medicine.

Tell your doctor if, for any reason, you have not taken Gabapentin exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

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

If you need to have any medical tests while you are taking Gabapentin, tell your doctor.

It may interfere with the results of some tests.

If you are going to have any surgery or procedure, including dental surgery, tell your surgeon, doctor or dentist that you are taking this medicine.

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

Your doctor will check your progress and may want to take some tests from time to time. This helps to prevent unwanted side effects.

Things you must not do

- **Do not give this medicine to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.**
- **Do not take your medicine to treat any other condition unless your doctor tells you to.**
- **Do not stop taking your medicine, or lower the dosage, without first checking with your doctor.**

Stopping gabapentin suddenly, if you have epilepsy, may cause unwanted effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

Things to be careful of

Be careful driving or operating machinery until you know how Gabapentin affects you.

As with other anticonvulsant medicines, Gabapentin may cause drowsiness, dizziness, light-headedness or sleepiness in some people. Make sure you know how you react to Gabapentin before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy.

Be careful when drinking alcohol while you are taking Gabapentin.

Combining Gabapentin and alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest you avoid alcohol while you are being treated with Gabapentin.

Side Effects

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

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

It can be difficult to tell whether side effects are the result of taking Gabapentin, of your condition; or side effects of other medicines you may be taking for this reason it is important to tell your doctor of any change in your condition.

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

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

If you get any side effects, do not stop taking gabapentin without first talking to your doctor or pharmacist.

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

- dizziness* or light-headedness
- feeling tired or drowsy*
- unfriendliness*
- unusually overactive*
- feeling agitated
- forgetfulness, loss of concentration or confusion
- difficulty speaking
- changes in your weight*
- constipation, diarrhoea
- nausea and/or vomiting*, indigestion
- dry mouth, red swollen gums
- muscle pain or cramps, back pain
- swelling of the hands or feet or blocked nose
- fever*
- bronchitis*, lung infection*

- sore throat and discomfort when swallowing, coughing.

The above list includes the more common side effects of Gabapentin. They are usually mild and short-lived.

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

- weakness, unsteadiness when walking including falling, reduced coordination or slowed reactions
- unusual changes in mood* or behaviour such as restlessness, nervousness or excitement
- signs of new onset of, or increased irritability or agitation
- signs of depression
- seeing or hearing things that are not there, irrational thinking
- blurred or double vision, uncontrollable jerky eye movements, difficulty seeing
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- trouble breathing or shallow breaths (respiratory depression)
- loss of consciousness

The side effects in the above list marked * have been specifically reported in children taking gabapentin.

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.

- more frequent or more severe seizures (fits)
- chest pain, a very fast heart rate
- sudden signs of allergy such as rash, itching or hives, fever, swollen lymph glands, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing

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 else that is making you feel unwell.

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

Some of these side effects (for example, changes in thyroid function, structures of bones, high cholesterol, levels of sugar in your blood or blood pressure) can only be found when your doctor does blood tests from time to time to check your progress.

Do not be alarmed by the list of possible effects.

You may not experience any of them.

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 Gabapentin APOTEX capsules look like

Gabapentin capsules are available in 100 mg, 300 mg and 400 mg strengths.

Gabapentin 100 mg Capsules:

White/White coloured size '3' hard gelatin capsules, filled with white to off-white blend.

Gabapentin 300 mg Capsules:

Yellow/Yellow coloured size '0' with cap 'M' and body '300' printed with black ink, hard gelatin capsules, filled with white to off-white blend.

Gabapentin 400 mg Capsules:

Orange/Orange coloured size '0el' with cap 'M' and body '400' printed with black ink, hard gelatin capsules, filled with white to off-white blend.

Available in blister packs of 10, 20, 30, 50, 100, 150, 300, 500, 1000 capsules.

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

Ingredients

Active Ingredient:

Each capsule contains 100 mg, 300 mg or 400 mg of gabapentin as the active ingredient.

It also contains the following inactive ingredients:

- lactose monohydrate
- talc-purified
- starch maize
- gelatin
- titanium dioxide
- sodium lauryl sulfate
- iron oxide - yellow (300 mg / 400 mg)
- iron oxide - red (400 mg)
- purified water.

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

This medicine contains sugars as lactose monohydrate. May contain trace amounts of phenylalanine and sulfites.

Australian Registration Numbers

Gabapentin APOTEX 100 mg Capsules (blister pack): AUST R 304223

Gabapentin APOTEX 300 mg Capsules (blister pack): AUST R 304224

Gabapentin APOTEX 400 mg Capsules (blister pack): AUST R 304225

Sponsor

This medicine is sponsored in Australia by

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park, NSW 2113
Australia
Tel: (02) 8877 8333
Web: www1.apotex.com/au

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