

Gabapentin APOTEX 600mg & 800mg

Gabapentin Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Gabapentin APOTEX.

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 Gabapentin APOTEX against the benefits it is expected to 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 Gabapentin APOTEX is used for

What Gabapentin APOTEX does

Gabapentin APOTEX is used to control epilepsy in stabilised patients.

Epilepsy is a condition where you have repeated seizures (fits). There are many different types of seizures, ranging from mild to severe.

Gabapentin APOTEX is also used to treat neuropathic pain, a type of pain caused by damage to the nerves.

Gabapentin APOTEX belongs to a group of medicines called anticonvulsants.

How Gabapentin APOTEX works

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

Gabapentin APOTEX also has pain relieving effects.

Ask your doctor if you have any questions about why Gabapentin APOTEX has been prescribed for you.

Your doctor may have prescribed it in addition to your current therapy when your current treatment is no longer working as well.

Your doctor may have prescribed it for another reason.

Gabapentin APOTEX may lead to dependence on this medicine.

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

Use in children

Gabapentin APOTEX is not recommended for use in children

The safety and effectiveness of Gabapentin APOTEX in these age groups have not been established.

Before you take Gabapentin APOTEX

When you must not take it

Do not take Gabapentin APOTEX if you have an allergy to:

- any medicine containing gabapentin, the active ingredient in Gabapentin APOTEX
- 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 in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

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 or pharmacist.

Before you start to take Gabapentin APOTEX

Tell your doctor or pharmacist if you have allergies to any other medicines, especially barbiturates or any other anticonvulsant

medicines, foods, preservatives or dyes.

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

- Kidney problems
- Mixed seizure disorders that include absence seizures.

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

This medicine 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 breast-feeding or plan to breast-feed.

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

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

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.

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

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 APOTEX, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or

pharmacist will advise you accordingly.

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

- certain medicines used to treat stomach or duodenal ulcers, such as cimetidine
- 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 this medicine.

How to take Gabapentin APOTEX

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 box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many tablets you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

Your doctor may recommend that you start with a low dose of gabapentin using alternative brands and slowly increase the dose to the lowest amount needed to control your condition. Once your condition is stabilised Gabapentin APOTEX is used

How to take it

Note: - Gabapentin APOTEX is available as 600mg and 800 mg unscored tablets and should not be broken into half.

Swallow Gabapentin APOTEX whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

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

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

It does not matter if you take this medicine before or after food.

How long to take it

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

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

Do not stop taking this medicine or lower the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or holidays.

Stopping this medicine suddenly may cause unwanted effects or make your condition worse. 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 the dose 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 to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) 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 Gabapentin APOTEX.

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

You may need urgent medical attention.

Symptoms of an overdose may include you feel drowsy, weak, unsteady when walking, have double visions, slurred speech or diarrhoea.

While you are taking Gabapentin APOTEX

Things you must do

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

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

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

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 anti-epileptics such as Gabapentin APOTEX have had thoughts of harming or killing themselves.

Patients and caregivers should be alert and monitor for these effects.

Signs and symptoms of suicide include:

- 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 warning signs of suicide while taking Gabapentin APOTEX, contact your doctor or a mental health professional right away.

Tell your doctor if you feel this medicine is not helping your condition.

Your doctor may need to change your medicine.

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

Otherwise, your doctor may change your treatment unnecessarily.

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

If you need to have any medical tests while you are taking this medicine, 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 take Gabapentin APOTEX to treat any other complaints unless your doctor tells you to.

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 stop taking your medicine or lower the dosage without checking with your doctor.

Stopping Gabapentin APOTEX suddenly, 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 APOTEX affects you.

As with other anticonvulsant medicines, this medicine may cause dizziness, light-headedness, tiredness and drowsiness in some people.

Make sure you know how you react to Gabapentin APOTEX 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.

If you drink alcohol, dizziness or light-headedness may be worse.

This medicine may cause drowsiness, dizziness or sleepiness in some people and affect alertness.

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

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

Side effects

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

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

may need medical attention if you get some the side effects.

It can be difficult to tell whether side effects are the result of taking Gabapentin APOTEX, effects 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.

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.

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

Tell your doctor if...

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
- 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
- Runny or blocked nose
- Fever
- Bronchitis, lung infection
- Sore throat and discomfort when swallowing, coughing.

The above list includes the more common side effects of your

medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if...

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

- Weakness, unsteadiness when walking including falling, reduced co-ordination 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.

Go to hospital if....

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- 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 also occur in some people.

Some of these side effects (for example, changes in thyroid function, structure of bones, high cholesterol 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 side effects.

You may not experience any of them.

After taking Gabapentin APOTEX

Storage

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

If you take the tablets out of the pack they will not keep well.

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

Do not store Gabapentin APOTEX or any other medicine in the bathroom or near a sink.

Do not leave Gabapentin APOTEX on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least 1½ metres above the ground is a good place to store medicines.

Disposal

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

Product description

What it looks like

Gabapentin APOTEX is available in two strengths

Gabapentin APOTEX 600mg (AUST R 306886) - White to off white, oval shaped, film coated tablets plain on both sides.

Gabapentin APOTEX 800mg (AUST R 306887) - White to off white, capsule shaped, film coated tablets plain on both sides.

Each pack contains 100 tablets.

Ingredients

Active ingredient

- 600 mg Gabapentin
- 800 mg Gabapentin

Other ingredients

The tablets also contain:

- Starch maize
- Copovidone
- Poloxamer
- Ethanol
- Hydroxypropyl cellulose
- Magnesium stearate
- Talc-purified

Gabapentin APOTEX does not contain sucrose, gluten, tartrazine or any other azo dyes.

Name and Address of the Sponsor

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne VIC 3000

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