

APO-Gabapentin Capsules

Contains the active ingredient gabapentin

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 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 your medicine may be available.

Ask your doctor or pharmacist if:

- 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 is this medicine used for

The name of your medicine is APO-Gabapentin Capsules. It contains the active ingredient, gabapentin.

It is used to:

- 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 it 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.

There is evidence that this medicine can lead to dependence.

Use in children

Gabapentin is not recommended for use 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, throat or other parts of the body; rash, itching or hives on the skin; fainting (due to very low blood pressure, which needs emergency treatment).

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 if 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:
 - kidney problems
 - mixed seizure disorders that include absence seizure
 - a history of dependence or addictive behaviour associated with prescription or non-prescription products.
3. You currently are pregnant or intend 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. 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 breastfeed.

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.

Taking other medicines

Some medicines may interact with gabapentin. These include:

- cimetidine, a medicine used to treat stomach or duodenal ulcers, or reflux
- antacids, medicines used to treat heartburn or reflux.
- morphine or other similar pain killers, as this may cause over sedation and difficulty breathing (especially in the elderly).

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 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 will depend on 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 without first checking with your doctor.

How to take it

Swallow gabapentin capsules whole 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.

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

If you forget to take it

If you have missed a dose by more than 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 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 may feel drowsy, weak, and unsteady when walking, lose consciousness, have double vision, slurred speech or diarrhoea.

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 breastfeed
- you are about to have any medical or blood tests
Gabapentin may affect the results of some tests.
- you are going to have surgery or an anaesthetic or are going into hospital
- gabapentin is not helping your condition.
Your doctor may need to change your medicine.

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:

- 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.
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

Suicidal thoughts or behaviours

Treatment with antiepileptic medicines is associated with a risk of suicidal thoughts and behaviour; available data suggest that the increased risk applies to all antiepileptic medicines and may be seen as early as 1 week after starting treatment. However suicidal thoughts and actions can also be from other causes.

There is no need to stop treatment on the basis of this new information unless your doctor says so. Stopping these medicines suddenly can cause serious problems. Anyone who is concerned about their treatment should talk to their doctor first.

Pay close attention to any day-to-day changes in mood, behaviour and actions. These changes can happen very quickly so it is important to be mindful of any sudden differences.

Be aware of common warning signs that might be a signal for risk of suicidal behaviour. Some of these are:

- talking or thinking about wanting to hurt one's self or end one's life
- becoming preoccupied with death and dying
- becoming depressed or having depression get worse
- becoming aggressive, irritable or agitated, or displaying an increase in such behaviour
- withdrawing from friends and family
- giving away prized possessions.

Mention of suicide or violence must be taken seriously.

If you or someone you know is demonstrating these warning signs and symptoms of suicide while taking this medicine seek medical advice immediately.

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

As with other anticonvulsant medicines, gabapentin may cause dizziness, light-headedness, tiredness or drowsiness in some people.

Be careful when drinking alcohol while taking this medicine.

Combining this medicine with alcohol can make you more sleepy, dizzy or light-headed.

Your doctor may suggest you avoid alcohol while you are being treated with gabapentin.

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

Possible 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.

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.

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

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

- 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.

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:

- weakness, unsteadiness when walking, reduced coordination or slowed reactions

- mood changes* such as restlessness, agitation, nervousness, irritability or excitement, 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.

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

Most of these side effects are rare.

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:

- more frequent or more severe seizures (fits)
- chest pain, a very fast heart rate
- aching muscles, muscle tenderness or weakness not caused by exercise, particularly if you also have a fever or generally feel unwell.

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

Allergic reactions

If you think you are having an allergic reaction to gabapentin, 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:

- 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 (very low blood pressure - needs emergency treatment).

Other side effects not listed above may also occur in some people. Some of these side effects (for example, changes in liver function) can only be found when your doctor does tests from time to time to check your progress.

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-Gabapentin looks like

APO-Gabapentin 100 mg Capsules:

Hard gelatin capsules with white opaque body and a white opaque cap. "Apo 112" is imprinted on each capsule in black ink.

Available in bottles of 100 capsules.

APO-Gabapentin 300 mg Capsules:

Hard gelatin capsules with white opaque body and a yellow opaque cap. "Apo 113" is imprinted on each capsule in black ink.

APO-Gabapentin 400 mg Capsules:

Hard gelatin capsules with white opaque body and an orange opaque cap. "Apo 114" is imprinted on each capsule in black ink.

Available in blister packs of 100 capsules.

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

Ingredients

Active Ingredient:

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

They also contain the following inactive ingredients:

- croscarmellose sodium
- magnesium stearate
- purified talc (300mg & 400mg capsules only)
- purified talc (300mg & 400mg capsules only)
- titanium dioxide
- gelatin
- Iron oxide yellow (300 mg & 400 mg capsules)
- Iron oxide red (400mg capsules only)
- Black printing ink (SW-9008/SW-9009)

In addition, the black printing ink (SW-9008/SW-9009) contains the following ingredients:

- shellac
- isopropyl alcohol
- tert-butyl alcohol
- propylene glycol
- ammonia
- black iron oxide
- potassium hydroxide
- purified water.

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

Australian Registration Numbers

APO-Gabapentin 100 mg Capsules (bottle):

AUST R 151318

APO-Gabapentin 300 mg Capsules (blister pack):

AUST R 81776

APO-Gabapentin 400 mg Capsules (blister pack):

AUST R 81777

Sponsor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park, NSW 2113

Australia.

APO and APOTEX are registered trade marks of Apotex Inc.

This leaflet was prepared in: June 2017.