

# Apo-Gabapentin

*gabapentin*

100mg, 300mg & 400mg Capsules and 600mg & 800mg Tablets

---

## What is in this leaflet

---

Please read this leaflet carefully before you start using Apo-Gabapentin.

This leaflet answers some common questions about Apo-Gabapentin. 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 using Apo-Gabapentin against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

---

## What Apo-Gabapentin is used for

---

The name of your medicine is Apo-Gabapentin. It contains the active ingredient gabapentin.

Apo-Gabapentin 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).

### ***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 Apo-Gabapentin for another reason.

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

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

**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 use Apo-Gabapentin**

---

### ***When you must not use it***

Do not use Apo-Gabapentin 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: cough, shortness of breath, wheezing, difficulty breathing or tightness in chest; 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.**  
If you take it after the expiry date has passed, it may have no effect at all, or worse, there may be an entirely unexpected effect.
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

If you are not sure whether you should start using Apo-Gabapentin, talk to your doctor.

### ***Before you start to use it***

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 are currently pregnant or you plan to become pregnant.**

Gabapentin can pass across the human placenta and 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 breast-feed.**

Gabapentin can pass into breast milk and may affect your baby. 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.**

If you have not told your doctor about any of the above, tell them before you start using Apo-Gabapentin.

### ***Taking other medicines***

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Apo-Gabapentin.

Some medicines may interfere with Apo-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).

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

Other medicines not listed above may also interact with gabapentin.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Apo-Gabapentin.

---

## How to use Apo-Gabapentin

---

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

The label should be carefully read

### ***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 the capsules or tablets whole with a full glass of water.

### ***When to take it***

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

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.

Gabapentin can be taken before, with or after food. Food or lack of food does not alter the rate of absorption significantly.

**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***

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.

Abrupt cessation of Gabapentin therapy should be avoided. 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

Your doctor will advise you when you can stop taking Apo-Gabapentin completely.

### ***If you forget to take it***

If you have missed a dose by more than 4 hours, 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.

---

## **While you are using Apo-Gabapentin**

---

### ***Things you must do***

Immediately stop taking Apo-Gabapentin and check with your doctor if a skin rash or other allergic reaction occurs.

Tell your doctor that you are taking this medicine if:

- 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.

Take your medicine exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking this medicine.

Visit your doctor regularly. Your doctor needs to check your progress and see whether you need to keep taking Apo-Gabapentin.

Always discuss with your doctor any problems or difficulties during or after taking Apo-Gabapentin.

Tell your doctor if for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough Apo-Gabapentin to last weekends and holidays.

### ***Things you must not do***

**Do not give Apo-Gabapentin to anyone else, even if 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 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

**Do not take any other medicine while you are taking Apo-Gabapentin without first telling your doctor.**

**Do not take Apo-Gabapentin for a longer time than your doctor has prescribed.**

### ***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.

Do not drive, operate machinery, or participate in any dangerous activities where alertness is required, until you know how Apo-Gabapentin affects you.

If you are being treated with opioids (e.g. morphine) at the same time as taking gabapentin you should be carefully observed for signs of central nervous system depression. Signs to look out for would be sleepiness, sedation and slow or shallow breathing. If these occur the dose of gabapentin or opioid should be reduced appropriately.

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.

---

## **In case of overdose**

---

### ***If you take too much (overdose)***

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Apo-Gabapentin.

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.

---

## **Side Effects**

---

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Apo-Gabapentin or if you have any questions or concerns.

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

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

Gabapentin is generally well tolerated.

**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, diarrhea
- 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.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

---

## **After using Apo-Gabapentin**

---

### ***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.

No special requirements for disposal.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

---

## Product description

---

### ***What it looks like***

#### **APO-Gabapentin 100mg Capsules:**

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

#### **APO-Gabapentin 300mg 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 400mg Capsules:**

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

#### **APO-Gabapentin 600mg Tablets:**

White, oval biconvex tablets. Engraved "GAB" over Partial bisect "600" on one side, "APO" on the other side.

#### **APO-Gabapentin 800 mg Tablets:**

White, oval biconvex tablets. Engraved "GAB" over Partial bisect "800" on one side, "APO" on the other side.

Apo-Gabapentin 100mg, 300mg and 400mg capsules are available in bottles of 100 capsules.

Apo-Gabapentin 600mg and 800mg tablets are available in bottles or blisters of 100 or 500 tablets.

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

### ***Ingredients***

#### **Active ingredient:**

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

Each tablet contains 600mg or 800mg of Gabapentin as the active ingredient.

#### **Inactive ingredients:**

APO-GABAPENTIN 100mg, 300mg and 400mg capsules contain the following inactive ingredients:

- Croscarmellose Sodium
- Magnesium stearate
- Purified talc (300mg & 400mg only)
- Gelatin (capsule)
- Titanium dioxide
- Iron oxide yellow (300mg & 400mg only)
- Iron oxide red (400mg only)
- Black ink (SW-9008/SW-9009)

The black printing ink contains the following ingredients: shellac, ethanol, isopropyl alcohol, tert-Butyl alcohol, propylene glycol, ammonia, black iron oxide, potassium hydroxide and purified water.

APO-GABAPENTIN 600mg and 800mg tablets contain the following inactive ingredients:

- Copovidone (Polyvinylpyrrolidone-vinyl acetate copolymer)
- Magnesium stearate
- Hypromellose (Hydroxypropyl methylcellulose)
- Hypolose (Hydroxypropyl cellulose)
- Macrogol 8000 (Polyethylene glycol 8000)
- Titanium dioxide

Apo-Gabapentin capsules and tablets are gluten free and lactose free

---

## Sponsor Details

---

Apo-Gabapentin is supplied in New Zealand by:

**Apotex NZ Ltd**  
32 Hillside Road  
Glenfield  
AUCKLAND 0627

Telephone: (09) 444 2073

Fax: (09) 444 2951

Email: NZcustomerservice@apotex.com

---

## Date of Preparation

---

This leaflet was prepared on 13 March 2018.