

# **Apo-Gabapentin Capsules**

Contains the active ingredient, Gabapentin (gab-a-PEN-tin)

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**For a copy of a large print leaflet, Ph: 1800 195 055**

## **Consumer Medicine Information**

### **What is in this leaflet**

**Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.**

This leaflet answers some common questions about gabapentin capsules.

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. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

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.

**Keep this leaflet with your medicine.**

You may want to read it again.

## **What gabapentin is used for**

The name of your medicine is Apo-Gabapentin. 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).

## **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.

**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.

There is no evidence that this medicine is addictive

## **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 gabapentin**

### **When you must not take it**

**Do not take this medicine if you 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; muscle pain or tenderness or joint pain or rash, itching or hives on the skin.

**Do not take this medicine after the expiry date (EXP) printed on the pack.**

If you take this medicine after the expiry date has passed, it may not work as well.

**Do not take this medicine if the packaging is torn, shows signs of tampering or if 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 this medicine, talk to your doctor or pharmacist.**

## **Before you start to take 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.

**3. You 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. If it is necessary for you to take this medicine, your doctor can help you decide whether or not to take it during pregnancy.

#### **4. You are breast-feeding or plan to breast-feed.**

Your doctor will discuss the possible risks and benefits of using this medicine during breast-feeding.

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

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

**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 buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and gabapentin may interfere with each other. These include:

- cimetidine, a medicine used to treat stomach or duodenal ulcers, or reflux

- antacids, medicines used to treat heartburn or reflux.
- morphine.

These 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 and pharmacist can tell you if you are taking any of these medicines. They may also have more information on medicines to be careful with or avoid while taking gabapentin.

Other interactions not listed above may also occur.

## **How to take this medicine**

Follow all directions given to you by your doctor or pharmacist carefully.

They 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 or pharmacist will tell you how many capsules you will need to take. This depends on 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 and then slowly increase the dose to the lowest amount needed to control your epilepsy or neuropathic pain.

## **How to take it**

**Swallow gabapentin capsules 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 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 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 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 the Poisons Information Centre (Tel: 13 11 26 for Australia) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much 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, unsteady when walking, have double vision, slurred speech or diarrhoea.

## **While you are taking gabapentin**

### **Things you must do**

**Tell any other doctors, dentists, and pharmacists who are treating you that you are taking gabapentin.**

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

**Before you have any surgery or emergency treatment, tell your doctor or your dentist that you are taking gabapentin.**

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

Gabapentin may affect the results of some tests.

**Tell your doctor if you feel gabapentin is not helping your condition.**

Your doctor may need to change 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.**

**Go to your doctor regularly for a check-up.**

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

## **Things you must not do**

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

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

Do not stop taking your medicine, or change the dosage, without checking with your doctor.

**Do not let yourself run out of medicine over the weekend or on holidays.**

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
- Withdrawing from friends and family
- Giving away prized possessions

**If any of the above happens 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.**

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

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

**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.**

## **Side effects of gabapentin**

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

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

This medicine helps most people with epilepsy or neuropathic pain, but it may have unwanted side effects in a few people.

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

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

**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\*
- 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
- 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:**

- 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.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

**If any of the following happen, 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 allergic reactions, such as itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing.

These are very serious side effects. You may need urgent medical attention or hospitalisation. Mostly, these side effects are very rare.

**Tell your doctor or pharmacist if you notice anything 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 liver function) can only be found when your doctor does tests from time to time to check your progress.

## **After taking this medicine**

### **Storage**

**Keep your medicine in its original packaging until it is time to take it.**

If you take the capsules out of the original packaging, they may not keep well.

**Keep your medicine in a cool dry place where the temperature stays below 25 degrees C.**

**Do not store your medicine, or any other medicine, in the bathroom or near a sink.**

**Do not leave it on a windowsill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it 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, ask your pharmacist what to do with any medicine that is left over.**

## **Where to go for further information**

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

## **Product description**

### **What Apo-Gabapentin looks like**

Apo-Gabapentin capsules are available in 100 mg strength.

## **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.

## **Ingredients**

### **Active Ingredient:**

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

They also contain the following inactive ingredients:

- croscarmellose sodium
- magnesium stearate
- purified talc
- titanium dioxide
- gelatin
- 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: AUST R 151318

## **Sponsor**

Apotex Pty Ltd

ABN 52 096 916 148

66 Waterloo Road

North Ryde NSW 2113

Australia

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