

# GenRx Gabapentin Capsules & Tablets

*Gabapentin (gab-a-PEN-tin)*

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## Consumer Medicine Information

For a copy of a large print leaflet Ph 1800 195 055

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### What is in this leaflet

This leaflet answers some common questions about GenRx Gabapentin Capsules and Tablets.

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 to you of taking GenRx Gabapentin against the benefits it is expected to have for you.

**If you have any concerns about taking GenRx Gabapentin, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What GenRx Gabapentin is used for

This medicine 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).

GenRx 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 GenRx Gabapentin in addition to your current treatment when your current treatment is no longer working as well.

Your doctor may have prescribed it for another reason.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

There is no evidence that GenRx Gabapentin is addictive.

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

GenRx 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.

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### Before you take GenRx Gabapentin

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

**Do not take GenRx Gabapentin if you have an allergy to:**

- **the active ingredient, gabapentin**
- **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.

**Do not take GenRx Gabapentin after the expiry (EXP) 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.

#### ***Before you start to take it***

**Tell your doctor if you have allergies to:**

- any other medicines, especially any other anticonvulsant medicines

- 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 are pregnant or intend to become pregnant.**

GenRx 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 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 him/her before you start taking GenRx Gabapentin.**

### ***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 GenRx 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 GenRx Gabapentin, 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.

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

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## **How to take GenRx Gabapentin**

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### ***How much to take***

Your doctor will tell you how many capsules or tablets you will 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 GenRx Gabapentin and then slowly increase the dose to the lowest amount needed to control your epilepsy or neuropathic pain.

**Carefully follow all directions given to you by your doctor or pharmacist.**

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 to take it***

**Swallow GenRx Gabapentin capsules/tablets whole with a full glass of water.**

GenRx Gabapentin tablets can be divided in half along the breakline, if advised by your doctor or pharmacist.

### ***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 GenRx 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.

### ***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.**

### ***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.

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

**Immediately telephone your doctor or the Poisons Information Centre (Australia - telephone 13 11 26) for advice, or go to the Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much GenRx Gabapentin.**

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

You may need urgent medical attention.

If you take too much of GenRx Gabapentin, you may feel drowsy, weak, unsteady when walking, have double vision, slurred speech or diarrhoea.

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## While you are taking GenRx Gabapentin

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### **Things you must do**

**Tell any other doctors, dentists, or pharmacists who treat you that you are taking GenRx Gabapentin.**

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

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

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

GenRx Gabapentin may affect the results of some tests.

**Tell your doctor if you feel GenRx 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 GenRx Gabapentin exactly as prescribed.**

Otherwise, your doctor may change your treatment unnecessarily.

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

**Be sure to 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 prevent unwanted side effects.

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

**Do not give GenRx Gabapentin 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 complaints unless your doctor tells you to.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

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

Stopping GenRx 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**

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

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

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

Do not drive if you feel dizzy or light-headed.

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

**Be careful when drinking alcohol while taking this medicine.**

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

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## Side effects

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

This medicine helps most people with epilepsy or neuropathic pain, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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 GenRx 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 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:**

- 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 GenRx Gabapentin.

**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. 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.

**Do not be alarmed by the above lists of side effects.**

You may not experience any of them.

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## After taking GenRx Gabapentin

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### Storage

**Keep your capsules/tablets in the original packaging until it is time to take them.**

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

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

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

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

Heat and dampness can destroy some medicines.

**Keep GenRx Gabapentin 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 the expiry date has passed, 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.

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## Product description

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### What GenRx Gabapentin looks like

#### Capsules

GenRx Gabapentin capsules are available in 300 mg & 400 mg strengths.

GenRx Gabapentin 300 mg Capsules are hard gelatin capsules with white opaque body and a yellow opaque cap. "Apo 113" is imprinted on each capsule in black ink.

GenRx Gabapentin 400 mg Capsules are hard gelatin capsules with white opaque body and an orange opaque cap. "Apo 114" is imprinted on each capsule in black ink.

The capsules are available in blister packs of 100 capsules per pack.

#### Tablets

GenRx Gabapentin tablets are available in 600 mg & 800 mg strengths.

GenRx Gabapentin 600 mg Tablets are white, oval biconvex tablets. Engraved "GAB" over European bisect "600" on one side, "APO" on the other side.

GenRx Gabapentin 800 mg Tablets are white, oval biconvex tablets. Engraved "GAB" over European bisect "800" on one side, "APO" on the other side.

The tablets are available in blister pack of 100 tablets per pack.

### Ingredients

#### Active Ingredient:

#### Capsules

GenRx Gabapentin 300 mg Capsules contain 300 mg of gabapentin as the active ingredient.

GenRx Gabapentin 400 mg Capsules contain 400 mg of gabapentin as the active ingredient.

**Tablets**

GenRx Gabapentin 600 mg Tablets contain 600 mg of gabapentin as the active ingredient.

GenRx Gabapentin 800 mg Tablets contain 800 mg of gabapentin as the active ingredient.

**Other Ingredients:****Capsules**

- croscarmellose sodium
- magnesium stearate
- purified talc
- titanium dioxide
- gelatin
- iron oxide yellow (CI 77492)
- Black printing ink (SW-9008/SW-9009)
- Iron oxide red (CI 77491) (400 mg capsules only).

**Tablets**

- copovidone
- magnesium stearate
- hypromellose
- hydroxypropylcellulose
- macrogol 8000
- titanium dioxide.

These medicines do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

**Australian Registration Numbers****Capsules**

GenRx Gabapentin 300 mg Capsules, in blister pack:

AUST R 81776.

GenRx Gabapentin 400 mg Capsules, in blister pack:

AUST R 81777.

**Tablets**

GenRx Gabapentin 600 mg Tablets, in blister pack:

AUST R 131470.

GenRx Gabapentin 800 mg Tablets, in blister pack:

AUST R 131508.

**Sponsor**

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Australia

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