

Gabapentin Sandoz®

gabapentin capsules

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Gabapentin Sandoz.

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 risk of you taking this medicine against the benefits they expect it will 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 SANDOZ IS USED FOR

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

It contains the active ingredient gabapentin and 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 may also be used to 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.

Gabapentin Sandoz also has analgesic effects.

This medicine is not addictive.

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

Gabapentin Sandoz is not recommended for the use in children under the age of 3 years to control epilepsy, or in children under the age of 18 years for the treatment of neuropathic pain. The safety and effectiveness of Gabapentin Sandoz in these age groups have not been established.

BEFORE YOU TAKE GABAPENTIN SANDOZ

When you must not take it

Do not take this medicine if you have an allergy to:

- gabapentin, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.
- any other similar medicines especially barbiturates or any other anticonvulsant medicines.

Some of the 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 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.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, 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 seizures.

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

Gabapentin Sandoz 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 will discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Your doctor will discuss the possible risks and benefits of using this medicine during breastfeeding. Gabapentin Sandoz passes into breast milk. The effect on your breast-fed baby is unknown.

If you do breastfeed, watch your baby carefully. If your baby

develops a skin rash or has unusual symptoms, don't breastfeed 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 Gabapentin Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Gabapentin Sandoz 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
- opioids, medicines used to control severe pain e.g. morphine.

These medicines may be affected by Gabapentin Sandoz, 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 have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE GABAPENTIN SANDOZ

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, ask your doctor or pharmacist for help.

How much to take

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

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Gabapentin Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the capsules whole with a full glass of water.

When to take Gabapentin Sandoz

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 Sandoz 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 need to take an antacid, take it at least 2 hours before or 2 hours after your dose of Gabapentin Sandoz.

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. It is

important to keep taking your medicine even if you feel well.

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

Stopping Gabapentin Sandoz suddenly may cause unwanted side 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

Take your dose as soon as you remember, and continue to take it as you would normally.

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.

Do not take a double dose to make up for the dose 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 when 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 (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much Gabapentin Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include drowsiness, unsteadiness, dizziness, double vision, slurred speech, lethargy, low blood pressure or diarrhoea.

WHILE YOU ARE TAKING GABAPENTIN SANDOZ

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 Sandoz.

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 this medicine.

It may affect other medicines used during surgery.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Tell your doctor if you feel that Gabapentin Sandoz is not helping your condition.

Tell your doctor if for any reason you have not taken this medicine as prescribed. Otherwise, your doctor may change your treatment unnecessarily.

Persons taking Gabapentin Sandoz may be more likely to think about killing themselves or actually trying to do so, especially when Gabapentin Sandoz is first started or the dose is changed.

Tell your doctor immediately if you have thoughts about killing yourself or if you are close to or care for someone using Gabapentin Sandoz who talks about or shows signs of killing him or herself.

All mentions of suicide or violence must be taken seriously.

Patient and care givers should pay attention for any of the following warning signs of suicide-related behaviour while taking Gabapentin Sandoz. Contact a health care provider immediately, or even go to the nearest hospital for treatment:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation.

Things you must not do

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

Do not give your medicine to anyone else, even if they have the same condition as you.

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

Things to be careful of

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

As with other anticonvulsant medicines, Gabapentin Sandoz may cause drowsiness, dizziness, light-headedness or sleepiness in some people. Make sure you know how you react to this medicine 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.

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

If you drink alcohol, it may worsen your dizziness, light-headedness or drowsiness. Your doctor may suggest you avoid alcohol while you are being treated with Gabapentin Sandoz.

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

SIDE EFFECTS

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

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.

It can be difficult to tell whether side effects are the result of taking this medicine; 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 the following lists of 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 Sandoz 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*
- being unusually overactive*
- forgetfulness, loss of concentration or confusion
- difficulty speaking
- changes in your weight*
- constipation or diarrhoea
- nausea and/or vomiting*, indigestion
- dry mouth, red swollen gums
- muscle pain or cramps
- back pain
- swelling of hands, ankles 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 Gabapentin Sandoz. They are usually mild and short-lived.

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

- weakness, unsteadiness when walking including falling, reduced coordination 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, or 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.

The side effects marked * have been especially reported in children taking gabapentin.

If any of the following happen, tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as rash, itching or hives, fever, swollen lymph glands, swelling of the face, lips, mouth, tongue or throat or other parts of the body, shortness of breath, wheezing or which may cause difficulty in swallowing or breathing
- more frequent or more severe seizures (fits)
- chest pain
- fast or irregular heart beats.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

All of 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, structures of bones, high cholesterol, levels of sugar in your blood or blood pressure) can only be found when your doctor does blood tests from time to time to check your progress.

AFTER TAKING GABAPENTIN SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store Gabapentin Sandoz 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 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Gabapentin Sandoz 300 mg are yellow capsules, available in blister packs of 100 capsules.

Gabapentin Sandoz 400 mg are brown capsules, available in blister packs of 100 capsules.

Ingredients

Active ingredient:

- Gabapentin Sandoz 300mg - 300mg gabapentin.
- Gabapentin Sandoz 400mg - 400mg gabapentin.

Inactive ingredients:

- pregelatinised maize starch
- maize starch
- purified talc
- colloidal anhydrousilica
- titanium dioxide
- sodium lauryl sulfate
- gelatin
- iron oxide yellow
- iron oxide red (400mg capsule only).

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
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 Australia
 Tel: 1800 726 369

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Australian Register Numbers

300mg capsules: AUST R 157197 (blisters)

400mg capsules: AUST R 157195 (blisters)