

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about GABATINE.

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 taking GABATINE 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 GABATINE is used for

GABATINE 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.

GABATINE is also used to treat neuropathic pain.

GABATINE belongs to a group of medicines called anticonvulsants. These drugs are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

GABATINE also has analgesic effects.

Your doctor may prescribe GABATINE in addition to your current therapy when your current treatment is no longer working as well.

Your doctor may have prescribed GABATINE for another reason. Ask your doctor if you have any questions about why GABATINE has been prescribed for you.

There is no evidence that GABATINE is addictive.

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

GABATINE is not recommended for use in children under the age of 3 years to control epilepsy, as its safety and effectiveness in that age group have not been established. Also, the safety and effectiveness of GABATINE for the treatment of neuropathic pain in children under the age of 18 years have not been established.

Before you take GABATINE

When you must not take it

Do not take GABATINE if you have an allergy to:

- gabapentin, the active ingredient in GABATINE or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to GABATINE 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 GABATINE after the expiry date (EXP) printed on the pack.

Do not take GABATINE 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 GABATINE, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines, especially barbiturates or any other anticonvulsant medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney problems
- mixed seizure disorders.

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

GABATINE 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 GABATINE, 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 breastfeed.

Your doctor will discuss the possible risks and benefits of using GABATINE during breastfeeding.

If you do breastfeed, watch your baby carefully.

If your baby develops a skin rash, becomes sleepy or has unusual symptoms, don't breastfeed again until you speak to your doctor.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking GABATINE.

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 GABATINE may interfere with each other.

These include:

- some medicines used to treat stomach or duodenal ulcers, such as cimetidine
- antacids, medicines used to treat heartburn or reflux.

These medicines may be affected by GABATINE, 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 and pharmacist may have more information on medicines to be careful with or avoid while taking GABATINE.

How to take GABATINE

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 GABATINE and slowly increase the dose to the lowest amount needed to control your epilepsy/convulsions or neuropathic pain.

Follow all directions given to you by your doctor carefully.

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 GABATINE whole with a full glass of water.

When to take it

Take GABATINE at about the same time each day.

Taking GABATINE at the same time each day will have the best effect.

It will also help you remember when to take the capsules.

It does not matter if you take GABATINE before or after food.

If you forget to take it

If it is almost time for your next dose (within 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 GABATINE for as long as your doctor tells you to.

GABATINE helps control your condition, but does not cure it. Therefore you must take your medicine every day, even if you feel well.

Do not stop taking GABATINE, or lower the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

Stopping GABATINE suddenly may cause unwanted effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much GABATINE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking GABATINE

Things you must do

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

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking GABATINE.

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

Tell your doctor if you feel GABATINE is not helping your condition.

Your doctor may need to change your medicine.

Tell your doctor if, for any reason, you have not taken GABATINE exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

If you become pregnant while taking GABATINE, tell your doctor.

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

GABATINE may affect the results of some tests.

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 to prevent unwanted side effects.

Things you must not do

Do not give GABATINE to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

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

Do not stop taking GABATINE unless your doctor tells you to.

Things to be careful of

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

As with other anticonvulsant medicines, GABATINE may cause dizziness, light-headedness, tiredness, drowsiness in some people. Make sure you know how you react to GABATINE 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. If you drink alcohol, dizziness or light-headedness may be worse.

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

GABATINE may cause drowsiness, dizziness or sleepiness in some people and affect alertness.

Be careful when drinking alcohol while taking GABATINE.

Combining GABATINE and alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest you avoid alcohol while you are being treated with GABATINE.

Side effects

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

GABATINE 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 treatment 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 GABATINE 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
- weakness, unsteadiness when walking, reduced co-ordination or slowed reactions
- decreased feeling in the skin or sensitivity
- mood changes such as restlessness, agitation, nervousness, irritability or excitement, depression
- seeing or hearing things that are not there, irrational thinking

- forgetfulness, loss of concentration or confusion
- difficulty speaking
- changes in appetite
- indigestion
- changes in your weight
- constipation, diarrhoea
- dry mouth
- coughing
- rash
- changes in breast size
- muscle pain or cramps
- swelling of the hands, ankles and feet
- blurred or double vision, uncontrollable jerky eye movements, difficulty seeing.

These are the more common side effects of GABATINE. Mostly these are mild and short-lived.

Tell your doctor immediately if you experience any of the following:

- suicidal thoughts
- suicide attempts.

Tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital if you have any thoughts of harming yourself or committing suicide.

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, palpitation
- sudden signs of allergy such as rash (called anaphylactic reactions), itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing
- severe stabbing or throbbing pain in the head
- nausea, vomiting, loss of appetite and feeling generally unwell, together with fever, itching and yellowing of the eyes and skin
- dark coloured urine.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people. Some of these side effects (for example, changes in thyroid function, structure of bones, high cholesterol or blood pressure) can only be found when your doctor does blood tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using GABATINE

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they will not keep well.

Keep your capsules in a cool dry place where the temperature stays below 25°C.

Do not store GABATINE or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car on hot days.

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 or pharmacist tells you to stop taking GABATINE or the capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

GABATINE comes in 3 strengths of capsules:

- GABATINE 100 – white capsule marked with “GA 100” and “>>”
- GABATINE 300 – yellow capsule marked with “GA 300” and “>>”
- GABATINE 400 – orange capsule marked with “GA 400” and “>>”.

Each pack contains 100 capsules.

Ingredients

The active ingredient in GABATINE is gabapentin.

- each GABATINE 100 capsule contains 100 mg of gabapentin
- each GABATINE 300 capsule contains 300 mg of gabapentin
- each GABATINE 400 capsule contains 400 mg of gabapentin.

The capsules also contain:

- lactose
- purified talc
- maize starch
- gelatin
- titanium dioxide
- iron oxide yellow (300 mg/400 mg)
- iron oxide red (400 mg)
- Opacode A-R-10561FD blue printing ink.

Sponsor

Sigma Pharmaceuticals (Australia) Pty Ltd
96 Merrindale Drive
Croydon Vic 3136
Tel: 03 - 9839 2800

Australian Registration

Numbers:

100 mg capsules: AUST R 107472
300 mg capsules: AUST R 107494
400 mg capsules: AUST R 107498

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