

GABITRIL® tablets

Tiagabine hydrochloride monohydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about GABITRIL. 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 GABITRIL 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 GABITRIL is used for

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

This medicine belongs to a group of medicines called antiepileptics or anticonvulsants.

It works by increasing the level of a chemical in the brain (gamma-aminobutyric acid, or GABA). This controls the signals in nerve cells so that seizures do not happen.

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 not addictive.

It is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 12 years.

Before you take it

When you must not take it

Do not take GABITRIL if you have an allergy to:

- any medicine containing tiagabine
- any of the ingredients listed at the end of this leaflet.

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:

- if you have severe liver disease
- in combination with St John Wort (*hypericum perforatum*).

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:

- anxiety disorders
- depression

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

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

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 GABITRIL may interfere with each other. These include:

- some other medicines used to treat epilepsy, such as phenytoin, carbamazepine, phenobarbitone and primidone
- St John Wort (*hypericum perforatum*).

These medicines may be affected by GABITRIL 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 it

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 pack, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This may depend on your condition and what other antiepileptic medicines you are taking.

Your doctor may recommend that you start with a low dose and slowly increase the dose to the lowest amount needed to control your epilepsy.

How to take it

Swallow the tablets with a full glass of water.

When to take it

Take your medicine at about the same times each day.

Taking it at the same times each day will have the best effect. It will also help you remember when to take it.

Take your medicine during or immediately after a meal.

If you take GABITRIL on an empty stomach, it may cause stomach upset.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to 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 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 this medicine suddenly may make your condition worse. If you do need to stop taking it, your doctor may slowly reduce your dose before you stop taking it completely.

If you forget to take it

If it is almost time for your next dose, 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 (telephone 131126) for advice or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much GABITRIL. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include sleepiness, dizziness, tremor, unsteadiness when walking, incoordination, impaired consciousness, agitation, hostility, aggression, confusion, disorientation, difficulty in speaking, vomiting, difficulty in

breathing, headache, urinary incontinence, temporary paralysis, increased seizures and coma and non-convulsive status epilepticus (prolonged and repeated fits or seizures without any recovery between attacks).

While you are taking it

Things you must do

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

- increasing signs of depression
- unusual changes in mood or behaviour
- suicidal thoughts
- suicidal behaviour
- thoughts about self-harm.

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

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Tell your doctor if you feel this medicine is not helping your condition.

Your doctor may need to change your medicine.

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

Otherwise, your doctor may change your treatment unnecessarily.

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

Things you must not do

Do not take GABITRIL 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, unless your doctor tells you to.

Things to be careful of

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

This medicine may cause dizziness and tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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

If you drink alcohol, dizziness or tiredness may be worse.

Side effects

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

This medicine helps most people with epilepsy, 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.

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.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dizziness
- tiredness
- nervousness (for no apparent reason)
- tremor
- difficulty in concentrating
- diarrhoea
- hostility

- difficulty in speaking.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- skin rash
- feeling depressed
- problems with your vision
- seeing, feeling or hearing things that are not there
- unusual bleeding or bruising, for example bruises that appear for no apparent reason.

The above list includes serious side effects which may require medical attention. Serious side effects are uncommon.

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

- an increase in the number of seizures, or different types of seizures to those you have had before
- if you have never had a seizure before but have since developed seizures while on this treatment.

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

Storage

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

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25C. Do not refrigerate the tablets.

Do not store GABITRIL 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

GABITRIL 5 mg tablets are white, round, biconvex film-coated tablets (marked 251).

GABITRIL 10 mg tablets are white, oval, biconvex film-coated tablets (marked 252).

GABITRIL 15 mg tablets are white, oval, biconvex film-coated tablets (marked 253).

Available in bottles of 50 tablets.

Ingredients

GABITRIL tablets contain 5 mg, 10 mg or 15 mg of tiagabine (as tiagabine hydrochloride monohydrate) as the active ingredient.

They also contain:

- colloidal anhydrous silica
- microcrystalline cellulose
- ascorbic acid
- pregelatinised maize starch
- crospovidone
- vegetable oil (hydrogenated)
- stearic acid
- lactose
- hypromellose
- magnesium stearate
- hyprolose
- titanium dioxide.

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

Sponsor

Teva Pharma Australia Pty Ltd
37 Epping Rd
Macquarie Park, NSW, 2113
Australia

GABITRIL is a registered trade mark of Novo Nordisk A/S used under licence by Teva Pharma Australia Pty Ltd

Australian Registration Numbers:

GABITRIL 5 mg, AUST R 120271

GABITRIL 10 mg, AUST R
120272

GABITRIL 15 mg, AUST R
120273.

This leaflet was revised in February 2018.