

GABITRIL®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using GABITRIL?

GABITRIL contains the active ingredient tiagabine hydrochloride monohydrate. GABITRIL 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.

For more information, see Section [1. Why am I using GABITRIL?](#) in the full CMI.

2. What should I know before I use GABITRIL?

Do not use if you have ever had an allergic reaction to tiagabine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use GABITRIL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with GABITRIL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use GABITRIL?

- Your doctor or pharmacist will tell you how many tablets you will need to take each day.
- GABITRIL should be taken at the same times each day. Take your medicine during or immediately after a meal. Swallow the tablets with a full glass of water.

More instructions can be found in Section [4. How do I use GABITRIL?](#) in the full CMI.

5. What should I know while using GABITRIL?

Things you should do	
	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist

	<p>you visit that you are using GABITRIL.</p> <ul style="list-style-type: none"> • Tell your doctor if you feel this medicine is not helping your condition.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly or lower the dosage, unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how GABITRIL affects you. • GABITRIL may cause dizziness and tiredness in some people.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol. Alcohol may worsen dizziness or tiredness.
Looking after your medicine	<ul style="list-style-type: none"> • 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 25°C
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For more information, see Section [5. What should I know while using GABITRIL?](#) in the full CMI.

6. Are there any side effects?

Common less serious side effects include tiredness, dizziness, nervousness (for no apparent reason), difficulty in concentrating, hostility, difficulty in speaking, tremor and diarrhoea.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

GABITRIL®

Active ingredient(s): *tiagabine hydrochloride monohydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using GABITRIL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using GABITRIL.**

Where to find information in this leaflet:

- [1. Why am I using GABITRIL?](#)
- [2. What should I know before I use GABITRIL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use GABITRIL?](#)
- [5. What should I know while using GABITRIL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using GABITRIL?

GABITRIL contains the active ingredient tiagabine hydrochloride monohydrate. GABITRIL is a medicine that 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.

GABITRIL 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.

2. What should I know before I use GABITRIL?

Warnings

Do not use GABITRIL if:

- you are allergic to tiagabine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- You have severe liver disease.
- You are taking St John Wort (hypericum perforatum).

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.

Check with your doctor if you:

- have any other medical conditions, including anxiety disorders and depression.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children

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

3. What if I am taking other medicines?

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

Some medicines may be affected by GABITRIL or may affect how GABITRIL works.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect GABITRIL.

4. How do I use GABITRIL?

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.
- Follow the instructions provided and use GABITRIL until your doctor tells you to stop.

When to take GABITRIL

- GABITRIL should be taken at the same times each day.
- Take your medicine during or immediately after a meal. If you take GABITRIL on an empty stomach, it may cause stomach upset.
- Swallow the tablets with a full glass of water

- 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 use GABITRIL

GABITRIL should be used regularly at the same times each day.

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 you missed.

If you use too much GABITRIL

If you think that you have used too much GABITRIL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre

(by calling 13 11 26), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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).

5. What should I know while using GABITRIL?

Things you should do

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.

Call your doctor straight away 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.
- become pregnant.

Remind any doctor, dentist or pharmacist you visit that you are using GABITRIL.

Things you should not do

- Do not stop using this medicine suddenly or lower the dosage, unless your doctor tells you to.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how GABITRIL affects you.

GABITRIL may cause dizziness and tiredness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may worsen dizziness or tiredness.

Looking after your medicine

- 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 25°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Related to Central Nervous System:</p> <ul style="list-style-type: none">• tiredness• dizziness• nervousness (for no apparent reason)• difficulty in concentrating• hostility• difficulty in speaking <p>Other:</p> <ul style="list-style-type: none">• tremor• diarrhoea	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Skin or bleeding-related:</p> <ul style="list-style-type: none">• skin rash• unusual bleeding or bruising, for example bruises that appear for no apparent reason	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>Mood or vision-related:</p> <ul style="list-style-type: none"> • feeling depressed • problems with vision • seeing, feeling or hearing things that are not there <p>Condition-related:</p> <ul style="list-style-type: none"> • an increase in the number of seizures, or different types of seizures to those you have had before 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What GABITRIL contains

Active ingredient (main ingredient)	Tiagabine hydrochloride monohydrate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• colloidal anhydrous silica• microcrystalline cellulose• ascorbic acid• pregelatinised maize starch• crospovidone• vegetable oil (hydrogenated)• stearic acid• lactose• hypromellose• magnesium stearate• hyprolose

- | | |
|--|--|
| | <ul style="list-style-type: none">• titanium dioxide |
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Do not take this medicine if you are allergic to any of these ingredients.

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

What GABITRIL looks like

GABITRIL 5 mg tablets (AUST R 120271) are white, round, biconvex film-coated tablets (marked 251).

GABITRIL 10 mg tablets (AUST R 120272) are white, oval, biconvex film-coated tablets (marked 252).

GABITRIL 15 mg tablets (AUST R 120273) are white, oval, biconvex film-coated tablets (marked 253).

Available in bottles of 50 tablets.

Who distributes GABITRIL

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Rd

Macquarie Park, NSW, 2113

Ph: 1800 288 382

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