

**GABITRIL® 5 mg,
Film-coated Tablets**
(Tiagabine hydrochloride)

**GABITRIL® 10 mg,
Film-coated Tablets**
(Tiagabine hydrochloride)

**GABITRIL® 15 mg,
Film-coated Tablets**
(Tiagabine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What GABITRIL is and what it is used for
2. What you need to know before you take GABITRIL
3. How to take GABITRIL
4. Possible side effects
5. How to store GABITRIL
6. Contents of the pack and other information

1. What GABITRIL is and what it is used for

GABITRIL is an anti-epileptic medicine. Tiagabine, the active substance in GABITRIL, increases the level of gamma-aminobutyric acid (GABA) in the brain, which prevents or reduces the number of seizures (epileptic events).

GABITRIL is used to help control epilepsy in adults and adolescents over 12 years old with partial seizures.

It is taken in combination with other medicines when these are not effective enough alone.

2. What you need to know before you take GABITRIL

Do not take GABITRIL:

- if you are allergic to tiagabine or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from severe liver disease.
- if you are taking St John's Wort

Warnings and precautions

Talk to your doctor or pharmacist before taking GABITRIL.

Take special care with GABITRIL if you:

- Stop taking GABITRIL because it may cause a recurrence of seizures. Do not stop taking GABITRIL without consulting your doctor.
- Feel anxious or depressed, or have done so in the past then these symptoms may get worse or appear again during treatment with GABITRIL. You must tell your doctor if you feel absent, depressed or anxious.
- Notice an increase in the number of seizures or new types of seizures you should contact your doctor. He will advise you on any changes that may need to be made to your treatment.
- Notice a serious rash, including fluid filled pimples or blisters, or if you notice spontaneous bruising or blackening of the skin, contact your doctor immediately.
- Notice any visual disorders, you should contact your doctor.
- Have been told by your doctor that you have an intolerance to some sugars, you should not take GABITRIL because it contains lactose.
- Have mild or moderate liver disorders, your doctor will have to adapt the dose of GABITRIL prescribed.

A small number of people being treated with anti-epileptics such as GABITRIL have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

If you experience (or have experienced) any of these symptoms, please tell your doctor.

Children

Do not give Gabitril to children below 12 years.

Other medicines and GABITRIL

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including:

- Other anti-epileptic medicines like phenytoin, carbamazepine, phenobarbital and primidone, because they may weaken and shorten the effects of GABITRIL.
- Rifampicin (medicine for treatment of tuberculosis), because it may weaken and shorten the effects of GABITRIL.
- St John's Wort.

In case of combination with one or several of these drugs, your doctor may adapt the dose of GABITRIL.

GABITRIL with food and drink

You should take GABITRIL tablets during a meal or snack.

Pregnancy and breast-feeding

As a precautionary measure, it is preferable not to take GABITRIL during pregnancy or breast-feeding.

Inform your doctor if you become pregnant or are planning to have a baby.

Driving and using machines

You should discuss with your doctor whether it is safe for you to drive or operate machinery. GABITRIL may cause dizziness, sleepiness or tiredness, especially at the beginning of the treatment. Do not drive a vehicle or operate machinery if you are feeling dizzy, sleepy or tired.

GABITRIL contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take GABITRIL

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

GABITRIL tablets should be swallowed with a glass of water, during a meal or snack.

When you first start using GABITRIL, your doctor will work with you to find the dose that will control your epilepsy. You will begin by taking GABITRIL tablets once or twice a day. The dose will then be gradually increased until it is sufficient to control your epilepsy.

Once your dose has been established, you may need to take GABITRIL tablets two or three times a day. The dosage on starting treatment with GABITRIL is 5 to 10 mg daily and it is increased weekly by 5 to 10 mg daily.

The average maintenance dose can range between 15 and 45 mg per day but higher doses may sometimes be prescribed.

If you have mild or moderate liver disorders, your doctor will have to adjust the dose of GABITRIL.

GABITRIL tablets may be used with caution for treatment in the elderly. Your doctor will decide if it is the best treatment for you.

If you take more GABITRIL than you should

The symptoms of overdosage with GABITRIL are headache, becoming mute (silent) and withdrawn, loss of memory, vomiting (being sick), hostility, increased salivary flow, inability to stop passing urine, difficulty controlling movements, sleepiness, dizziness, confusion, feeling agitated, aggressive behaviour, uncontrolled movements of the eye, impaired speech, impaired memory, hallucinations (seeing or hearing things that are not there), odd beliefs, slower or faster heart beat, low or high blood pressure, shaking or tremors, abnormal involuntary movements (dyskinesia), involuntary contraction of muscles, twitching, seizures (fits), loss of consciousness, difficulty in breathing or stopping breathing and coma.

If you have taken too many tablets or if a child has taken any, immediately contact your doctor or the nearest hospital.

If you forget to take GABITRIL

If you have forgotten to take a dose, continue with the treatment as prescribed by your doctor.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking GABITRIL

You should continue to take GABITRIL for as long as indicated by your doctor.

Do not stop treatment with GABITRIL without having first informed your doctor, because there is a risk of recurrence of seizures. Your doctor will explain to you how to gradually reduce the dose (over 2-3 weeks).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects are generally mild to moderate. Most occur during the first few months of the treatment and are often short-lived. These may include:

Very common side effects (occurring in more than 1 in 10 people):

- Dizziness

- Tremor
- Feeling nervous
- Tiredness
- Feeling sick (nausea)

Common side effects (occurring in less than 1 in 10 people, but more than 1 in 100):

- Diarrhoea, being sick (vomiting), abdominal pain
- Difficulty in sleeping, feeling over-emotional
- Acting in a hostile or aggressive way
- Difficulty in controlling movements; walking, stepping or running oddly; difficulty speaking
- Muscle twitching
- Blurred vision
- Difficulty in concentrating
- Feeling depressed
- Slowness of speech
- Confusion
- Accidental injury

Uncommon side effects (occurring in less than 1 in 100, but more than 1 in 1,000):

- Loss of reality
- Drowsiness
- Bruising
- Severe blistering rash. If you notice any skin complaints, contact your doctor immediately.

Rare side effects (occurring in less than 1 in 1,000 people, but more than 1 in 10,000):

- A state of epilepsy that continues without any fitting
- Visual defects
- Hallucinations
- False beliefs

Unknown (exact frequency cannot be estimated from the available data)

- Encephalopathy (lethargy, confusion, with or without seizures)
- Serious rash, including fluid filled pimples or blisters; or a severe rash with reddening and peeling of skin
- Temporary loss of memory

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store GABITRIL

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box and bottle. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package.

Take this medicine out of its packaging only when you are ready to use it.

Do not use this medicine if you notice the tablets have changed in appearance (e.g. if their colour changes: they are normally white).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What GABITRIL contains

- The active substance is tiagabine anhydrous, present in the medicine as hydrochloride monohydrate.

Each GABITRIL 5 mg tablet contains 5 mg of tiagabine anhydrous.

Each GABITRIL 10 mg tablet contains 10 mg of tiagabine anhydrous.

Each GABITRIL 15 mg tablet contains 15 mg of tiagabine anhydrous.

- The other ingredients are:

Tablet core:

Cellulose, microcrystalline (E 460), Ascorbic acid (E 300), Lactose, Starch, pregelatinised (maize), Crospovidone, Silica, colloidal anhydrous (E 551), Hydrogenated vegetable oil (Type 1), Stearic acid, Magnesium stearate,

Film-coating:

Opadry White, Hypromellose, Hydroxypropylcellulose (E 463), Titanium dioxide (E 171)

What GABITRIL looks like and contents of the pack

GABITRIL are white, round or oval and slightly curved film-coated tablets.

GABITRIL tablets are supplied in a plastic bottle with a screw-top with an embedded drying agent.

GABITRIL 5 mg tablets are marked "251".

GABITRIL 10 mg tablets are marked "252".

GABITRIL 15 mg tablets are marked "253".

GABITRIL tablets are supplied in bottles of 50 or 100 tablets. However not all pack sizes may be available in your country.

Marketing Authorisation Holder

Cephalon UK Limited, Ridings Point,
Whistler Drive, Castleford,
West Yorkshire, WF10 5HX, UK

Manufacturer

Balkanpharma Dupnitsa AD,
3 Samokovsko Shosse Str., Dupnitsa,
2600, Bulgaria

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