PACKAGE LEAFLET

Package leaflet: Information for the user

Gabitril 5 mg film-coated tablets
Gabitril 10 mg film-coated tablets
Gabitril 15 mg film-coated tablets

Tiagabine (as hydrochloride monohydrate)

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

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.
- in combination with a herbal preparations containing St. John's Wort (Hypericum perforatum). See 'Other medicines and Gabitril'.

Warnings and precautions
Talk to your doctor or pharmacist before taking Gabitril
- if you are under the age of 12 years.
- if you suffer from generalised epilepsy, as you may experience worsening of absences (short periods of clouding of consciousness).
- if you stop taking Gabitril because it may cause a recurrence of seizures. Do not stop taking Gabitril without consulting your doctor.

- if you 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.
- a small number of people being treated with anti-epileptics such as tiagabine have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.
- if you 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.
- if you 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.
- if you notice any visual disorders, you should contact your doctor as Gabitril may rarely lead to visual field defects.
- if you have been told by your doctor that you have an intolerance to some sugars, you should not take Gabitril because it contains lactose.
- if you have mild or moderate liver disorders, your doctor will have to adapt the dose of Gabitril prescribed.

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

Other medicines and Gabitril
Tell your doctor or pharmacist if you are taking or using, have recently taken orused or might take or use any other medicines.
If you are taking or have recently taken any of the following, talk to your doctor or pharmacist before starting Gabitril:
- Other anti-epileptic medicines like phenytoin, carbamazepine, phenobarbital and primidone, because they may weaken and shorten the effects of Gabitril.
- Herbal preparations containing St. John's Wort (Hypericum perforatum), as they must not be taken together with Gabitril (see 'Do not take Gabitril').
- Rifampicin (medicine for treatment of tuberculosis), because it may weaken and shorten the effects of Gabitril.

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

Gabitril with food and drink
You should take Gabitril tablets during a meal or snack.

Pregnancy, breast-feeding and fertility
As a precautionary measure, it is preferable not to take Gabitril during pregnancy or breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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. You should 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.
Dependent on other medicines you are taking, the average maintenance dose of Gabitril can range between 15 and 50 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 most common symptoms of overdose with Gabitril are seizures, mute (silent) and withdrawn, loss of memory, coma, difficulty coordinating movements, sleepiness, dizziness, confusion, impaired speech, agitation, tremors, abnormal involuntary movements (dyskinesia), involuntary contraction of muscles, vomiting and hostility.

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
- Sleepiness
- Feeling depressed
- Feeling nervous
- Difficulty in concentrating
- Tiredness
- Feeling sick (nausea)

Common side effects (occurring in less than 1 in 10 people, but more than 1 in 100):
- Diarrhoea
- Bruising (blackening of the skin). If you notice bruising, contact your doctor immediately

Uncommon side effects (occurring in less than 1 in 100 people, but more than 1 in 1000):

Rare side effects (occurring in less than 1 in 1000 people, but more than 1 in 10000):
- A state of epilepsy that continues without any fitting, a slow-down in brain activity measured by the electroencephalogram that is due to either a fast dose adjustment or increasing dose of the medicine
- Visual defects
- Confusion
- Hallucination
- Agitation
- False beliefs

Unknown (exact frequency cannot be estimated from the available data)
- Encephalopathy (lethargy, confusion, with or without seizures)
- Severe blistering rash. If you notice any skin complaints, contact your doctor immediately.
- Serious rash, including fluid filled pimples or blisters; or a severe rash with reddening and peeling of skin.
- Being sick (vomiting), abdominal pain
- Difficulty in sleeping, feeling overly emotional, acting in a hostile way
- Difficulty in controlling movements; walking, stepping or running oddly; difficulty speaking
- Muscle twitching
- Blurred vision
- temporary loss of memory

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Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie

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 Gabitril after the expiry date which is stated on the box and bottle after "EXP" (Expiry date). 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 Gabitril 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, present in the medicine as hydrochloride monohydrate.

Each Gabitril 5 mg film-coated tablet contains 5 mg of tiagabine.
Each Gabitril 10 mg film-coated tablet contains 10 mg of tiagabine.
Each Gabitril 15 mg film-coated tablet contains 15 mg of tiagabine.

- The other ingredients are:

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

Film-coating:
Hypromellose
Hydroxypropylcellulose (E 463)
Titanium dioxide (E 171)

What Gabitril looks like and contents of the pack

Gabitril are white film-coated tablets.

Gabitril 5 mg film-coated tablets are round and marked “251”.
Gabitril 10 mg film-coated tablets are oval and marked “252”.
Gabitril 15 mg film-coated tablets are oval and marked “253”.

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

Gabitril film-coated tablets are supplied in bottle of 20, 30, 50, 100 and 200 film-coated tablets. However not all pack sizes may be available in your country.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Teva Pharma B.V.
Swensweg 5
2031 GA Haarlem
The Netherlands.

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

This medicinal product is authorised in the Member States of the EEA under the following names:
Gabitril

This leaflet was last revised in May 2022.