**Package leaflet: Information for the user**

# Sabril® 500 mg film-coated tablets

*vigabatrin*

SANOFI

**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 sings 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 Sabril is and what it is used for

Sabril is used to help control various forms of epilepsy.
It is used together with your current medication to treat "difficult to control" epilepsy. It will initially be prescribed by a specialist. Your response to the treatment will be monitored.
It is also used to control infantile spasms (West's syndrome).

## 2. What you need to know before you take Sabril

**Do not take Sabril**
- if you are allergic to vigabatrin or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**

Talk to your doctor before taking Sabril if:
- You are breast feeding
- You are pregnant or plan to become pregnant
- You have or have had depression or any other psychiatric illness in the past
- You have had any kidney problems
- You have had any problems with your eyes

Visual field loss (loss of sight from the edges of your field of vision) may occur during treatment with Sabril. You should discuss this possibility with your doctor before you begin treatment with this medicine. This visual field loss may be severe and irreversible, so it must be found early. A deterioration of this visual field loss after the treatment is discontinued cannot be excluded. It is important that you inform your doctor promptly if you become aware of any change to your vision. Your doctor should perform a visual field examination before you start taking Sabril and at regular intervals during the treatment.

If you develop symptoms like sleepiness, reduced consciousness and movements (stupor) or confusion consult your doctor who will decide upon a dose reduction or withdrawal.

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

Children

Movement disorders have been seen in young infants treated for infantile spasms (West's syndrome). If you observe unusual movement disorders in the child, consult your doctor who will decide if it is necessary to consider changing the treatment.

**Other medicines and Sabril**

Please tell your doctor it you are taking clonazepam as the concomitant use with Sabril can increase the risk of sedation.
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Sabril should not be used in combination with other medicines that may have side effects related to the eye.

**Pregnancy, breast-feeding and fertility**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
Do not take Sabril during pregnancy unless your doctor tells you to. Sabril may cause problems to unborn children. However, do not stop taking the medicine suddenly because this may risk the mother's health as well as the baby's health.

Sabril passes into breast milk. If you are breast-feeding ask your doctor for advice before taking this medicine. Breast-feeding should not be done during treatment.

**Driving and using machines**

Do not drive or operate machinery if your epilepsy is uncontrolled.
Sabril sometimes causes symptoms like drowsiness or dizziness and your ability to concentrate and react may be reduced. If such symptoms occur whilst taking Sabril, you should not do any hazardous tasks such as driving or operating machinery.

Visual disorders, which can affect your ability to drive and use machines, have been found in some patients taking this medicine. If you wish to continue driving you must be tested regularly (every six months) for the presence of visual disorders even if you do not notice any changes to your vision.

## 3. How to take Sabril

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
It is important to follow your doctor's instructions exactly. Never change the dose yourself. The doctor prescribes the dose and adjusts it individually for patients.
The usual starting dose for adults is 1 g (2 tablets) daily. However, your doctor may wish to increase or decrease the dose depending on your response; the usual adult daily dose is 2 to 3 g (4 to 6 tablets). The highest recommended dose is 3 g/day.

If you are older people and/or have kidney problems, your doctor may wish to give you a smaller dose.

Use in children

*Resistant partial epilepsy*

For children, the dose is based on age and weight. The usual starting dose for children is 40 milligrams per kilogram bodyweight daily. The following table gives the number of tablets to give to a child according to his/her bodyweight. Remember that this is just a guideline. The child's doctor may wish to have slightly different doses.

| Bodyweight | | |
|---|---|---|
| | 10-15 kg | 0.5-1 g (1-2 tablets)/day |
| | 15-30 kg | 1-1.5 g (2-3 tablets)/day |
| | 30-50 kg | 1.5-3 g (3-6 tablets)/day |
| greater than | 50 kg | 2-3 g (4-6 tablets)/day (adult dose). |

*Children with infantile spasms (West's Syndrome)*

The recommended starting dose for infants with West's Syndrome (infantile spasms) is 50 milligrams per kilogram bodyweight per day although higher doses may be used sometimes.

Method of administration

The route of administration is oral use (by mouth).
Always swallow the tablet with at least a half of a drinking glass of water.
You can take Sabril before or after meals.
The daily dose can be taken as a single dose or divided in two doses.

**If you take more Sabril than you should**

If you or your child accidentally take too many Sabril tablets, tell your doctor immediately or go to your nearest hospital or Poison Information Centre. Possible signs of overdose include drowsiness or loss/depressed level of consciousness.

**If you forget to take Sabril**

If you forget to take a dose, take it as soon as you do remember. If it is almost time for your next dose, just take one dose. Do not take a double dose to make up for the missed dose.

**If you stop taking Sabril**

Do not stop taking this medicine without talking to your doctor. If your doctor decides to stop your treatment you will be advised to gradually reduce the dose. Do not stop suddenly as this may cause your seizures to occur again.

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.
As with other antiepileptic medicines, some patients may experience an increase in the number of seizures (fits) whilst taking this medicine. If this happens to you, or to your child, contact your doctor immediately.

**Talk to your doctor immediately if you experience:**
Very common side effects (may affects more than 1 in 10 people)
- Visual field changes – About ⅓ or 33 out of 100 patients treated with Sabril may have changes in the visual field (narrow visual field). This "visual field defect" can range from mild to severe. It is usually detected after months or years of treatment with Sabril. The changes in the visual field may be irreversible, so it must be found early. If you or your child experience(s) visual disturbances, contact your doctor or hospital immediately.

Other side effects include:
Very common side effects (may affect more than 1 in 10 people)
- Tiredness and pronounced sleepiness.
- Joint pain

Common side effects (may affect up to 1 in 10 people)
- Headache
- Weight gain
- Shaking (tremor)
- Swelling (oedema)
- Dizziness
- Sensation of numbness or tingling (pins and needles)
- Disturbance of concentration and memory
- Psychological disturbances including agitation, aggression, nervousness, irritability, depression, thought disturbance and paranoia, insomnia. These side effects are usually reversible when the dose is reduced or gradually discontinued. However, do not decrease your dose without first talking to your doctor. Contact your doctor if you experience these side effects.
- Nausea, vomiting and abdominal pain
- Blurred vision, double vision and rapid involuntary movement of the eye
- Speech disorder
- Decrease in the number of red blood cells (anaemia)
- Unusual hair loss or thinning (alopecia)

Uncommon side effects (may affect up to 1 in 100 people)
- Lack of coordination in movements or fumbling
- More severe psychological disturbances such as hypomania, mania and psychosis
- Skin rash

Rare side effects (may affect up to 1 in 1,000 people)
- Serious allergic reaction, which causes swelling of the face or throat: If you experience these symptoms, you should tell your doctor immediately.
- Hives or nettle rash
- Marked sedation, stupor and confusion. These side effects are usually reversible when the dose is reduced or gradually discontinued. However, do not decrease your dose without first talking to your doctor. Contact your doctor if you experience these side effects.
- Suicide attempt
- Other eye problems such as retinal disorder

Very rare side effects (may affect up to 1 in 10,000 people)
- Other eye problems such as optic neuritis and optic atrophy
- Hallucinations
- Liver problems

<u>Additional side effects in children</u>
Very common side effects (may affect more than 1 in 10 people)
- Excitation or restless

Not known frequency ( frequency cannot be estimated from available data)
Movement disorders in young infants treated for infantile spasm.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

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## 5. How to store Sabril

Keep out of the sight and reach of children.

Do not use Sabril after the expiry date which is stated on the outer cardboard box and blisters. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Sabril contains

- The active substance is vigabatrin. One film-coated tablet contains 500 mg vigabatrin.
- The other ingredients are:
  Tablet Core:
  Povidone K30 (E1201), Microcrystalline cellulose (E460), Sodium starch glycollate (type A), Magnesium stearate
  Tablet Coating:
  Hypromellose 15 mPa.s (E464), Titanium dioxide (E171), Macrogol 8000

### What Sabril looks like and contents of the pack

Sabril appears as white to off-white, oval, biconvex film-coated tablets with a break-line on one side and "Sabril" engraved on the other side.

It is available in clear blisters or opaque blisters of 10 tablets.

Each package contains 30, 50, 60, 100 or 200 tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder:

Sanofi-aventis Ireland Ltd., T/A SANOFI
Citywest Business Campus
Dublin 24 – Ireland
Tel.: 00 353 1 4035 600
Fax: 00 353 1 4035 687
Email: IEmedinfo@sanofi.com

### Manufacturer:

Patheon France S.A. Boulevard de Champaret
38300 Bourgoin-Jallieu – France

For any information about this medicine, please contact the Marketing Authorisation Holder.

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

**Austria:** Sabril 500 mg Filmtabletten
**Belgium:** Sabril 500 mg filmomhulde tabletten
**Denmark:** Sabrilex
**Finland:** Sabrilex 500 mg tabletti, kalvopäällysteinen
**France:** Sabril 500 mg comprimé pelliculé
**Germany:** Sabril 500 mg Filmtabletten
**Greece:** Sabril 500 mg επικαλυμμένα με λεπτό υμένιο δισκία
**Ireland:** Sabril 500 mg film-coated tablets
**Italy:** Sabril 500 mg compresse rivestite con film
**Luxembourg:** Sabril 500 mg comprimés pelliculés
**Netherlands:** Sabril 500 mg filmomhulde tablet
**Portugal:** Sabril 500 mg comprimidos revestidos por película
**Spain:** Sabrilex 500 mg comprimidos recubiertos con película
**Sweden:** Sabrilex 500 mg filmdragerade tabletter
**United Kingdom:** Sabril 500 mg film-coated tablets

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