

SABRIL[®] TABLET

Vigabatrin (500mg)

What is in this leaflet

1. What Sabril is used for
2. How Sabril works
3. Before you use Sabril
4. How to use Sabril
5. While you are using it
6. Side effects
7. Storage and disposal of Sabril
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Sabril is used for

Sabril is used to help control various form of epilepsy. Sabril is used as an add-on treatment for people whose epilepsy has not been well controlled by, or who cannot take, other antiepileptic medicines.

How Sabril works

Sabril contains a medicine called vigabatrin. Vigabatrin works by affecting the activity of a neurotransmitter called GABA (gamma-aminobutyric acid). Neurotransmitters are natural body chemicals that are stored in nerve cells. They are involved in transmitting messages between the nerve cells. GABA is a neurotransmitter that acts as a natural 'nerve calming' agent. It helps keep the electrical nerve activity in the brain in balance.

Vigabatrin prevents the breakdown of GABA in the brain. This enables GABA to calm the nerve activity in the brain for a longer period of time, which helps to prevent seizures.

Before you use Sabril

- When you must not use it

Do not take Sabril if

- You are allergic (hypersensitive) to vigabatrin or any of the other ingredients of Sabril (listed in section 8 below).

- Before you start to use it

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 had

these thoughts, immediately contact your doctor.

Check with your doctor or pharmacist before taking your medicine if:

- You are breast feeding
- You are pregnant or plan to become pregnant.
- You have or have had depression, behavioural disorders or any other psychiatric illness in the past
- You have had any kidney problems
- You are an elderly.
- 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 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.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription. Sabril should not be used in combination with other medicines that may have side effects related to the eye.

How to use Sabril

Always take Sabril exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- How much to use

Adults

- The usual starting dose for adults is 1g (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 3g (4 to 6 tablets).
- The highest recommended dose is 3g/day.

Children

- Tablets are not suitable for children under the age of 6 years, because of the risk of choking.
- The usual starting dose for children is 40 milligrams per kilogram bodyweight daily.
- Recommendations in relation to bodyweight for maintenance treatment are as follows:

10-15 kg	1-2 tablets/day
15-30 kg	2-3 tablets/day
30-50 kg	3-6 tablets/day
>50 kg	4-6 tablets/day.

Elderly

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

- When to use it

Take Sabril at about the same time each day unless your doctor tells you otherwise.

- Swallow the tablets orally with sufficient amounts of liquid (approximately 1/2 glass). Sabril can be taken with or without food.
- The daily dose can be taken as a single dose or divided in two doses.

- How long to use it

Continue taking your medicine for as long as your doctor tells you. Do not stop suddenly as this may cause your seizures to occur again.

- If you forget to use it

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten tablet.

- *If you use too much (overdose)*

If you take too many tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. The following effects may happen: drowsiness, coma, dizziness, headache, mental disorder, respiratory depression, slow heartbeat, low blood pressure, agitation, irritability, confusion, behavioural disorder and speech disorder.

While you are using it

- *Things you must do*

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Sabril.
- Tell your doctor immediately if you become pregnant while taking this medicine.
- Stop taking Sabril immediately if you are experiencing any disturbances of vision.

- *Things you must not do*

Pregnancy and breast-feeding

- Tell your doctor immediately if you are pregnant or plan to become pregnant during your treatment. Do not take Sabril during pregnancy unless your doctor tells you to. Sabril may cause problems to unborn children.
- Sabril can be found in breast milk. Therefore, breastfeeding is not recommended during treatment.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Sabril, or change the dosage, without checking with your doctor.

- *Things to be careful of*

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 individual 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.

Side Effect

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

Do not be alarmed by this list of possible side effects.

As with other antiepileptic medicines, some individual 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.

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

- About 1/3 or 33 out of 100 individual 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.
- Children may become over excited or restless.
- Feeling of lack of energy
- Drowsiness

Common side effects (affect between 1 and 10 individual in every 100 individual treated)

- Headache
- Weight gain
- Tremor
- Oedema (swelling)
- 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 feeling suspicious without reason (paranoia). These side effects are usually reversible when the dose is reduced or gradually discontinued.

- Nausea and abdominal pain
- Blurred vision, double vision, and uncontrolled movement of the eye, which may cause dizziness
- Speech disorder

Uncommon side effects (affect between 1 and 10 individual in every 1000 individual treated)

- Lack of coordination in movements or fumbling
- More severe psychological disturbances such as feeling elated or over-excited which causes unusual behaviour, and feeling detached from reality
- Skin rash

Rare side effects (affect between 1 and 10 individual in every 10,000 individual treated)

- Serious allergic reaction, which causes swelling of the face or throat
- Hives or nettle rash
- Marked sedation, stupor and confusion. These side effects are usually reversible when the dose is reduced or gradually discontinued.
- Suicide attempt
- Other eye problems such as retinal disorder, for example poor vision at night and difficulty adjusting from bright to dim areas, sudden or unexplained loss of vision, loss of sight from the edges of your field of vision, sensitivity to light.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Sabril

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

- Storage

- Keep out of the reach and sight of children.
- Do not use Sabril after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store in a cool place below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

The tablets are white to off-white, oval, biconvex tablets with a score line on one side and "SABRIL" engraved on the other side. The score line makes it possible to take half a tablet at a time if the whole tablet is difficult to swallow, but is not to be used to divide into two equal doses.

- Ingredients:

Active ingredient:

- The active substance is vigabatrin.
One-filmed coated tablet contains 500mg vigabatrin.

Inactive ingredients:

- The other ingredients are polyvinylpyrrolidone, microcrystalline cellulose, Sodium starch glycolate Ph.Eur., titanium dioxide, magnesium stearate, purified water, polyethylene glycol 8000 and hydroxypropyl methylcellulose.

- MAL number:

MAL19961357AZ

Manufacturer and Product Registration Holder

- Manufacturer

PATHEON FRANCE S.A.
40, Boulevard de Champaret
38300 Bourgoin-Jallieu, France.

- Product Registration Holder

Sanofi-aventis (Malaysia) Sdn. Bhd.
Unit TB-18-1,
Level 18-1, Tower B, Plaza 33
No.1 Jalan Kemajuan,
Seksyen 13,
46200 Petaling Jaya,
Selangor Darul Ehsan,
Malaysia.

Date of revision

6/12/2017

Serial number:

NPRA(R4/1)081117/00307