PATIENT INFORMATION LEAFLET

Visual field loss (loss of sight from the edges of your field of vision) has been reported in adults and children taking SABRIL. You should discuss this possibility with your doctor before you begin treatment with SABRIL.
Males are at greater risk than females. Most of the patients with confirmed visual defects did not experience symptoms. This visual field loss may be severe, up to tunnel vision or loss of vision, 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 and visual acuity testing before you start taking SABRIL and at regular intervals during the treatment. Your doctor may require from you to sign a form to acknowledge that this risk associated with the use of SABRIL has been discussed with you.

SABRIL may cause reduced vision due to eye problems such as retinal disorder, blurred vision, optic atrophy or optic neuritis (see section 4). If your vision changes consult your ophthalmologist.

SCHEDULING STATUS

S3

SABRIL TABLETS

film-coated tablets

vigabatrin

Sugar free

Read all of this leaflet carefully before you start taking SABRIL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SABRIL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What SABRIL is and what it is used for

SABRIL is used to help control various forms of epilepsy. SABRIL 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.

2. What you need to know before you take SABRIL

Do not take SABRIL:

- If you are allergic (hypersensitive) to vigabatrin or any of the other ingredients of SABRIL.
- If you are breastfeeding.
- If you may be pregnant, are pregnant or plan to become pregnant.
- If you have severe kidney problems.

Warnings and precautions

You should tell your doctor if:

- You have had any problems with your eyes.

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

You have or have had depression or any other psychiatric illness in the past.

If you develop symptoms like sleepiness, or confusion consult your doctor who will decide upon a dose reduction or withdrawal of SABRIL.

Other medicines and SABRIL

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

SABRIL should not be used in combination with other medicines that may have side effects related to the eye.

Do not share medicines prescribed for you with others.

SABRIL with food and drink

You can take SABRIL before or after meals.

Pregnancy and breastfeeding

If you are planning to become pregnant, you should talk to your doctor before taking SABRIL**.** Do not take SABRIL during pregnancy unless your doctor tells you to. SABRIL may cause problems to unborn children.

Tell your doctor immediately if you are pregnant or if you become pregnant during your treatment. However, do not stop taking SABRIL suddenly because this may risk the mother's health as well as the baby's health.

SABRIL can be found in breast milk. Therefore, breastfeeding is not recommended during treatment.

Driving and using machines

Do not drive or operate machinery if your epilepsy is not well controlled.

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 receiving SABRIL therapy. 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

Do not share medicines prescribed for you with any other person.

It is important to follow your doctor's instructions exactly. Never change the dose yourself. The doctor prescribes the dosage and adjusts it individually for the patients. Always swallow the tablet with at least a half of a drinking glass of water.

The usual starting dose for adults is 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.

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

For children, the dose is based on age and weight. The usual starting dose for children is 40 milligrams per kilogram body weight daily. The following table gives the number of SABRIL 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 a slightly different dose.

Body weight	10 – 15 kg	1 – 2 tablets/day 0,5 – 1 g/day
	15 – 30 kg	2 – 3 tablets/day 1 – 1,5 g/day
	30 – 50 kg	3 – 6 tablets/day 1,5 – 3 g/day
	greater than 50 kg	4 – 6 tablets/day 2 – 3 g/day (adult dose)

The daily dose can be taken as a single dose or divided in two doses.

You must see your doctor if your symptoms worsen or do not improve after 10 days.

If you have the impression that the effect of SABRIL is too strong or too weak, tell your doctor or pharmacist.

If you take more SABRIL than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison 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 forgotten individual doses.

If you stop taking SABRIL

Do not stop taking SABRIL 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.

4. Possible side effects

SABRIL can have side effects.

Not all side effects reported for SABRIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SABRIL, please consult your health care provider for advice.

Some patients may experience an increase in the number of seizures (fits) whilst taking SABRIL. If this happens to you, or to your child, contact your doctor immediately.

If any of the following happens, stop taking SABRIL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SABRIL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- About one third 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.
- Children may become over excited or restless
- Tiredness and pronounced sleepiness
- Joint pain
- 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), insomnia. These side effects are usually reversible when SABRIL doses are reduced or gradually discontinued. However, do not decrease your dose without first talking to your doctor. Contact your doctor if you experience these effects.
- Nausea, vomiting and abdominal pain
- Blurred vision, double vision, and rapid involuntary movement of the eye, which may cause dizziness
- Speech disorder
- Decrease in the number of red blood cell (anaemia)
- Unusual hair loss or thinning (alopecia)

Less frequent side effects:

- Lack of coordination in movements or fumbling
- Skin rash
- More severe psychological disturbances such as feeling elated or over-excited which causes unusual behaviour and feeling detached from reality.
- 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.
- Marked sedation, stupor and confusion. These side effects are usually reversible when SABRIL doses are reduced or gradually discontinued. However, do not decrease your dose without first talking to your doctor. Contact your doctor if you experience these effects.
- Hallucinations (feeling, seeing or hearing things that are not there)
- Other eye problems such as pain in your eyes (optic neuritis) and loss of vision, including colour vision (optic atrophy)
- Liver problems

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to:

- The Pharmacovigilance Unit at Sanofi: za.drugsafety@sanofi.com (email) or 011 256-3700 (tel), or
- SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of SABRIL.

5. How to store SABRIL

Store at or below 30 C°.

Store in the original container.

Do not use after the expiry date stated on the carton and blisters. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What SABRIL contains

The active substance is vigabatrin.

The other ingredients are:

Tablet Core: magnesium stearate, microcrystalline cellulose (E460), povidone K30 (E1201), sodium starch glycollate (type A).

Tablet Coating: hypromellose 15 mPa s (E464), macrogol 8000, titanium dioxide (E171).

What SABRIL looks like and contents of the pack

White to off-white, oval, biconvex tablet with a break line on one side and SABRIL inscribed on the other.

Blister packs of 100 tablets.

Holder of the certificate of registration

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