

PATIENT PACKAGE INSERT
IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only

Sabrilan Tablets

Each tablet contains 500 mg Vigabatrin.
Inactive ingredients and allergens in the medicine - see section 6.

Read this entire leaflet carefully before you start using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It might harm them, even if you think that their medical condition is similar to yours.

The medicine is not intended for infants and children weighing less than 10 kg.

During treatment with Sabrilan, visual field narrowing may develop. You should discuss this possibility with the doctor before starting treatment with Sabrilan. Narrowing of the visual field may be severe, to the point of tunnel vision or loss of vision, and irreversible, therefore it should be identified early. A deterioration of visual field loss even after treatment is discontinued cannot be ruled out. It is important to inform your doctor immediately if you notice any change to your vision. The doctor should perform a visual field examination and visual acuity testing before starting treatment with Sabrilan and at regular intervals during treatment.

Sabrilan can cause a reduction in vision due to eye problems such as a retinal problem, blurred vision, optic neuritis or optic atrophy (see section 4). If your vision changes, consult your ophthalmologist.

1. What is the medicine intended for?

For treatment of epilepsies in patients who do not respond adequately to other antiepileptic medicines as an adjuvant drug in combination with other antiepileptic medicines, when all other possible combinations have been proven to be inadequate or have not been tolerated.

Therapeutic group: Antiepileptic.

2. Before using the medicine

Do not use the medicine if:
• you are hypersensitive (allergic) to the active ingredient Vigabatrin or to any of the additional ingredients the medicine contains (see section 6).

Special warnings regarding the use of the medicine

Before treatment with Sabrilan, tell the doctor if:

- you are breastfeeding
- you are pregnant or planning to become pregnant
- you have or have had depression or any other psychiatric illness in the past
- you have had any kidney function problems
- you have had any problem with the eyes

If you develop symptoms such as sleepiness, reduced awareness and movements (stupor) or confusion, you should consult with the doctor in order for him to decide whether to reduce the dosage or discontinue treatment with Sabrilan. In a small number of patients treated with antiepileptics such as Sabrilan, thoughts with regard to self-harm or suicide have occurred. If you experience such thoughts at any time, refer to the doctor immediately.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Clonazepam. Taking clonazepam concomitantly with Sabrilan might increase the risk of sleepiness. It is not recommended to use Sabrilan in combination with other medicines that may cause eye-related side effects.

Use of the medicine and food
Sabrilan can be taken before or after meals.

Pregnancy, breastfeeding and fertility
If you are pregnant, think you may be

pregnant or are planning to become pregnant, consult your doctor before taking this medicine.

Do not take Sabrilan during pregnancy, unless instructed to do so by your doctor. Sabrilan may cause problems to the fetus. Nevertheless, do not stop taking the medicine abruptly, as that can endanger your health as well as your baby's health. Sabrilan passes into breast milk. If you are breastfeeding, consult your doctor before taking the medicine. Do not breastfeed during treatment with the medicine.

Driving and use of machines

Do not drive or operate machinery if your epilepsy is uncontrolled. Do not drive a car or operate dangerous machinery while using the medicine as using this medicine may sometimes cause symptoms such as drowsiness or dizziness, and the ability to concentrate and to react may decrease. If these symptoms occur while taking Sabrilan, do not perform any hazardous tasks such as driving or operating machinery. As for children, they should be warned against riding a bicycle or playing near roads etc.

Visual disorders that can affect the ability to drive or operate machinery have been found in a number of patients. If you wish to continue driving during treatment, you must regularly undergo eye examinations (every 6 months) for presence of visual disorders, even if you do not notice changes to your vision.

Important information about some of the ingredients of the medicine

The sodium amount in each tablet is less than 23 mg, therefore the medicine is essentially sodium free.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. You should check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only. The usual starting dosage is: **For adults:** 1 gram (2 tablets) per day. However, your doctor may increase or decrease the dosage depending on your response.

The usual daily dosage for adults is 2 to 3 grams (4 to 6 tablets). The highest recommended dosage is 3 grams per day.

If you are an elderly person and/or have kidney problems, your doctor may prescribe a lower dosage for you.

Use in children:

For children, the dosage is based on age and weight. The usual starting dosage for children is 40 mg per 1 kg bodyweight daily.

The following table shows the number of tablets to be given to a child according to his bodyweight. Remember that this is only a guideline. The pediatric doctor may slightly alter the dosage.

Body weight	Daily dose
10-15 kg	0.5-1 gram (1-2 tablets)
15-30 kg	1-1.5 grams (2-3 tablets)
30-50 kg	1.5-3 grams (3-6 tablets)
Over 50 kg	2-3 grams (4-6 tablets) (adult dose)

Do not exceed the recommended dose.

Method of administration:

The medicine is taken orally. Always swallow the tablet with at least half a glass of water.

In order to make swallowing easier, the tablet can be halved for immediate use, if necessary. Swallow the two halves one after the other immediately after halving. No data is available on crushing/mashing the tablet.

The daily dose can be taken as a single dose or be divided into two doses. Sabrilan can be taken before or after food.

Children: this medicine is intended for children weighing 10 kg or more. The tablets are not suitable for children under the age of 6 due to the risk of choking.

If you have accidentally taken a higher dosage

Possible signs of an overdose include drowsiness or reduced

awareness/loss of consciousness. If you have taken an overdose or if a child or someone else has accidentally swallowed the medicine, refer to a doctor or to a hospital emergency room immediately and bring the package of the medicine with you.

If you forgot to take the medicine

Take the dose as soon as you remember. If you remember close to the time of your next scheduled dose, take a single dose only at the usual time and consult with your doctor. Do not take a double dose to make up for a forgotten dose.

Adhere to treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking this medicine

Do not stop taking the medicine without speaking with your doctor about it. If your doctor decides to discontinue your treatment, it will be recommended you do so by gradually decreasing the dosage. Do not discontinue the treatment abruptly for fear of recurrence of epileptic seizures.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of Sabrilan may cause side effects in some patients. Do not be alarmed while reading the list of side effects. You might not suffer from any of them.

As with other antiepileptic medicines, some patients may experience an increase in the number of attacks during treatment. If you or your child experience/s this, refer to the doctor immediately.

Refer to the doctor immediately in the following cases:

Very common side effects (appear in more than one user out of 10):
• Visual field changes - About a third of patients (33 out of 100) treated with Sabrilan may experience changes in the visual field (narrowing of the visual field). This "visual field defect" can range from mild to severe. It is usually noticed after months or years of treatment with Sabrilan. These changes in the visual field may be irreversible, so they must be found early. If you or your child experience/s visual disturbances, refer to the doctor or a hospital immediately.

Additional side effects include:

Very common side effects (appear in more than one user out of 10):
• Tiredness and pronounced sleepiness.
• Joint pain.

Common side effects (appear in 1-10 users out of 100):

- Headache.
- Weight gain.
- Tremor.
- Swelling (Edema).
- Dizziness.
- Numbness or tingling sensation (pins and needles).
- Disturbance of concentration and memory.
- Psychological disturbances including: agitation, aggression, nervousness, irritability, depression, thought disturbances and feeling suspicious without reason (paranoia), insomnia. These side effects are generally reversible when the dose is reduced or is gradually discontinued. In any event, do not decrease dosage of your medicine without discussing with your doctor first. Notify the doctor if you experience these side effects.
- Nausea, vomiting and abdominal pain.
- Blurred vision, double vision and involuntary eye movements, which may cause dizziness.
- Speech disorder.
- A decrease in red blood cell count (anemia).
- Unusual hair loss or thinning (alopecia).

Uncommon side effects (appear in 1-10 users out of 1,000):

- Lack of coordination/clumsiness in movement.
- More severe psychological

disturbances such as feeling elated or over-excited, causing unusual behavior and a feeling of detachment from reality.
• Skin rash.

Rare side effects (effects that appear in 1-10 users out of 10,000):

- Serious allergic reaction, causing swelling of the face or neck: if you experience these symptoms, you must refer to the doctor immediately.
- Urticaria (an effect in which red, raised and itchy sores appear).
- Significant sleepiness (sedation), stupor and confusion. These side effects are usually reversible when the dose is reduced or is gradually discontinued. In any event, do not decrease dosage of your medicine without discussing it with your doctor first. Notify the doctor if you experience these side effects.
- Suicide attempt.
- Other eye problems such as a retinal problem for example, poor night vision, and difficulty in adjusting from bright light areas to dim light areas (difficulty in adjusting to different illumination conditions), sudden or unexplained loss of vision, loss of peripheral vision, sensitivity to light.

Very rare side effects (appear in less than one user out of 10,000):

- Other eye problems such as pain in the eyes (optic neuritis) and loss of vision, including loss of color vision (optic atrophy).
- Hallucinations (feeling, seeing or hearing things that do not exist).
- Liver problems.

Side effects whose frequency is unknown (the frequency cannot be determined from available data):
• Decrease in visual acuity

Additional side effects in children:
Very common side effects (appear in more than one user out of 10):
Excitation or restlessness

If a side effect appears, if one of the side effects worsens or when you suffer from a side effect not mentioned in this leaflet, you should consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health via the link "Reporting Side Effects of Drug Treatment" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link: <https://sideeffects.health.gov.il> Additionally, you can report to Perrigo via the following address: www.perrigo-pharma.co.il

5. How to store the medicine?

- Avoid poisoning! This medicine and all other medicines must be stored in a safe place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the carton and blister packages. The expiry date refers to the last day of that month.
- Store in a cool place, at a temperature below 25°C. Store in the original package.

6. Additional information

In addition to the active ingredient, the medicine also contains: Opadry® white OY-S-7298, microcrystalline cellulose, polyvinylpyrrolidone (povidone), sodium starch glycolate, magnesium stearate, hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol 8000.

- What the medicine looks like and contents of the package: Each package contains 50, 60 or 100 white to off-white oval, biconvex tablets, with a score line on one side and "Sabril" on the other side. The tablets are packed in blisters.
- Registration holder and manufacturer: Perrigo Israel Pharmaceuticals Ltd., P.O.B. 16, Yeruham.
- Revised in August 2020.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 5894.27254

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