

**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.  
Sodium amount in each tablet: not over 13.9 mg.  
Inactive ingredients - see section 6.

**Read this leaflet carefully in its entirety before taking the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

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

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

## 1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of epilepsy in patients who do not respond adequately to other antiepileptic medicines (as an adjuvant drug in combination with other antiepileptic medicines).

Therapeutic group: Antiepileptic.

## 2. BEFORE USING THE MEDICINE

### Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient Vigabatrin or to any of the additional ingredients contained in the medicine.

### Special warnings regarding use of the medicine

Do not use the medicine without consulting a doctor before starting treatment if you suffer, or have suffered in the past:

- From impaired function of the kidney.
- From depressions or any other psychiatric disorder.
- From eye problems.

As well as in the following cases:

- If you are pregnant or planning to become pregnant.
- If you are breastfeeding.

• 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 serious and irreversible, and therefore should be identified early on. Worsening of the condition even after treatment is discontinued cannot be ruled out. It is important to inform your doctor immediately if you note any change in your vision. The doctor should check your visual field before starting treatment with Sabrilan and at regular intervals during the course of treatment.

• If you develop symptoms such as sleepiness, drowsiness, reduction in awareness/alertness and in movements (stupor) or confusion, consult with the doctor who will decide whether to reduce the dosage or discontinue treatment with Sabrilan.

• In a small number of patients treated with antiepileptics such as Sabrilan, suicidal thoughts or thoughts about self injury have occurred. If you experience such thoughts, contact your doctor immediately.

**If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist.** It is particularly important to inform the doctor or pharmacist if you are taking:

Medicines that may cause eye-related side effects. It is not recommended to take Sabrilan concomitantly with these medicines.

### **Pregnancy and breastfeeding**

If you are planning to become pregnant, you should consult with the doctor before taking the medicine.

Do not take Sabrilan during pregnancy, unless instructed to do so by the doctor. Sabrilan may cause problems to the fetus. Notify the doctor immediately if you are pregnant or if you become pregnant during treatment. In any case, do not stop taking the medicine abruptly in order to prevent harm to yourself or to your baby.

Sabrilan passes into breast milk, therefore, breastfeeding is not recommended during the course of treatment with the medicine.

### **Driving and operating machinery**

Do not drive a car or operate dangerous machinery if your epilepsy is uncontrolled.

Use of this medicine may cause drowsiness and dizziness, and your ability to concentrate and react quickly may be impaired. If such symptoms occur, you should not drive a car nor operate dangerous machinery, nor undertake any activity that requires alertness. Children should be cautioned against bicycle riding or playing near roads and the like.

In a number of patients, visual disorders that could affect the ability to drive or operate machinery were detected. If you want to continue driving while under treatment, you must regularly undergo eye examinations every 6 months, even if you do not sense changes in vision.

## 3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain. **The dosage and treatment regimen will be determined by your doctor only.**

Swallow the medicine with plenty of water (at least half a glass of water).

The medicine may be taken before or after meals.

Those with swallowing difficulties: It is permissible to halve the tablets. However, do not to crush them.

Take the daily dose either as a single dose or in two doses. You should be under medical supervision during the course of treatment.

**Children:** This medicine is intended for children weighing 10 kg or more.

### **Do not exceed the recommended dose.**

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a hospital emergency room, and bring the package of the medicine with you. Symptoms of an overdose are: dizziness, reduced consciousness and fainting.

**If you forgot to take the medicine,** take the dose as soon as you remember. If you remember at the time of the next scheduled dose, only take a single dose that day. Do not take a double dose to compensate for a forgotten dose.

Adhere to the treatment regimen recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. In case the doctor indicates discontinuation of treatment with the medicine, this should be done by gradual reduction of 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 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, use of Sabrilan may cause side effects in some patients. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

As with other antiepileptic drugs, some patients may experience an increased number of attacks during treatment. If you or your child experiences this, **refer to the doctor immediately.**

You must contact the doctor immediately in the following cases:

Side effects occurring very frequently:

- About a third of the patients (33 out of 100) treated with Sabrilan may suffer from visual field changes (visual field narrowing). This visual defect can be mild to severe. It is generally noticed after months or years of treatment with Sabrilan. These visual field changes may be irreversible and therefore should be detected early on. If you or your child notice/s visual disturbances, **refer to the doctor or proceed to a hospital immediately.**

Additional side effects:

Side effects occurring frequently:

- In children, restlessness and over-excitation have been observed.
- Tiredness and significant drowsiness.
- Joint pains.
- Headache.
- Weight gain.
- Tremor.
- Edema (swelling).
- Dizziness.
- Numbness or tingling sensation.
- Concentration and memory problems.
- Psychological effects including: anxiety, aggression, nervousness, restlessness, depression, thinking disturbances and paranoia (false thoughts). These effects are generally reversible when the dosage is reduced or administration of the medicine is gradually discontinued. In any case, do not decrease the dosage of the medicine without consulting the doctor. Notify the doctor if you experience these side effects.
- Nausea, abdominal pain, vomiting.
- Blurred vision, double vision and rapid involuntary movements of the eye, which may lead to dizziness.
- Speech disturbances.
- Anemia (a decrease in red blood cell count).

Side effects occurring infrequently:

- Lack of coordination/clumsiness in movement.
- More severe psychological disturbances such as feeling elated or over-excited, leading to unusual behavior and a feeling of detachment from reality.
- Skin rash.

Side effects occurring rarely:

- Severe allergic reaction causing swelling of the face and neck - **if this happens, you must refer to the doctor immediately.**
- Urticaria (an effect in which red, raised and itchy sores appear).
- Significant reduction in alertness (sedation), stupor and confusion - these effects are usually reversible when the dosage is decreased or when administration of the medicine is gradually discontinued. In any case, do not reduce the dosage of the medicine without consulting with the doctor. Notify the doctor if you experience these side effects.
- Suicide attempts.
- Other eye problems such as retinal damage. For example, poor night vision, and difficulty in adjusting from bright to dim light (difficulty in adjusting to different illumination conditions), sudden or unexplained loss of vision, loss of peripheral vision, sensitivity to light.

Side effects occurring very rarely:

- Other eye problems such eye pain (inflammation of the optic nerve) and loss of vision as well as loss of color differentiation (optic atrophy).
- Hallucinations (feeling, seeing or hearing things that do not exist).
- Liver problems.

If any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

## 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order 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. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Polyvinyl pyrrolidone (povidone), microcrystalline cellulose, sodium starch glycolate, magnesium stearate, hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol 8000.

• What the medicine looks like and the 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.

• This leaflet was checked and approved by the Ministry of Health in February 2015.

• Registration number of the medicine in the National Drug Registry of the Ministry of Health: 5894.27254