

**PATIENT PACKAGE INSERT  
IN ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS  
(PREPARATIONS) - 1986**  
This medicine is dispensed with  
a doctor's prescription only

## Sabrilan Tablets

### Active ingredient:

Each tablet contains 500 mg  
Vigabatrin.

For a list of inactive ingredients  
and allergens in the medicine - see  
section 6 "Additional information".

**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 epilepsy 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:

- Colnazeepam. 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.

#### 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:

If you are experiencing symptoms  
of a severe allergic reaction, which  
causes swelling of the neck or  
the face, **refer to the doctor  
immediately.**

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
- Abnormal changes in MRI images  
of the brain.
- MRI images showing swelling in  
the protective layer of nerve cells  
in part of the brain.

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](http://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  
Padagis via the following address:  
<https://padagis.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:  
Microcrystalline cellulose,  
polyvinylpyrrolidone (povidone),  
sodium starch glycolate,  
magnesium stearate.  
Coating: Opadry® white  
OY-S-7298: 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. Not  
all package sizes may be marketed.
- Registration holder and  
manufacturer: Padagis Israel  
Pharmaceuticals Ltd., 1 Rakefet  
St., Shoham.
- Revised in July 2022 according to  
MOH guidelines.
- Registration number of the  
medicine in the National Drug  
Registry of the Ministry of Health:  
5894.27254

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