

## READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

### PATIENT MEDICATION INFORMATION

#### **SABRIL® (vigabatrin)**

Read this carefully before you or your child start taking Sabril and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Sabril.

#### **Serious Warnings and Precautions**

- Sabril can damage the vision of anyone who takes it.
- Sabril can result in a loss of peripheral vision (narrowing your vision) which may lead to permanent damage to eyesight.
- Before starting treatment with Sabril, you should discuss with your healthcare professional the potential benefits of this medicine versus the risk of damage to your vision.
- You/your child should have your eyes examined before beginning treatment with Sabril and at regular intervals (approximately every 3 months) thereafter.
- Tell your healthcare professional immediately about any change in your/your child's eyesight such as narrowing of your vision, blurred vision or any other visual symptoms.

#### **What is Sabril used for?**

Sabril belongs to the family of medicines called antiepileptic drugs and is used to treat:

- Partial epilepsies in combination with other anti-epileptic drugs when other antiepilepsy drug combinations have not worked
- Infantile spasms (West Syndrome)

Sabril should be used under close monitoring by a neurologist and an ophthalmologist.

#### **How does Sabril work?**

Sabril helps to control electrical activity in the brain. This reduces the chances of having seizures.

#### **What are the ingredients in Sabril?**

Medicinal ingredients: Vigabatrin

Non-medicinal ingredients (Tablets): Hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate and titanium dioxide.

Non-medicinal ingredients (Powder for Oral Solution (sachets)): Povidone.

Both the tablets and the sachets are lactose free.

**Sabril comes in the following dosage forms:**

Sabril Tablets, 500 mg

Sabril Powder for Oral Solution (sachets), 500 mg

**Do not use Sabril if:**

- You/your child are allergic to vigabatrin or any other ingredients of Sabril.
- You are pregnant or plan to become pregnant.
- You are breast-feeding or planning to breastfeed.

If you become pregnant while taking Sabril, talk to your healthcare professional about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic medicine during pregnancy. Information on the registry can also be found at the website <http://www.aedpregnancyregistry.org/>

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you/your child take Sabril. Talk about any health conditions or problems you/your child may have, including if you/your child:**

- Experience swelling
- Have a history of drug abuse
- Have ever had a rash or unusual reaction while taking vigabatrin or any other antiepileptic drug
- Have been told you have anemia (low red blood cell counts)
- Need Magnetic Resonance Imaging (MRI)
- Have a movement disorder. Movement disorders have been reported in patients treated with Sabril for infantile spasms
- Have symptoms of numbness or tingling or loss of feeling in the toes or feet
- Suffer from myoclonic seizures. Sabril may cause an increase in the number of seizures or cause new seizure types especially in people who have myoclonic seizures
- Have any eye or vision problems. Sabril can damage the vision of anyone who takes it
- Have had any mental illnesses in the past. Sabril may cause you to feel agitated, aggressive, depressed, paranoid or think abnormally
- Have ever tried or thought about committing suicide or if you or your child have or had depression, mood problems or suicidal thoughts or behaviour in the past
- Have, or have ever had any kidney problems
- Are 65 years of age or older

Other warnings you should know about:

- **Serious skin reactions (Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)):** Ask your healthcare professional about signs and symptoms of life threatening skin reactions such as Stevens-Johnson Syndrome (SJS; a skin reaction with rash and blisters) and Toxic Epidermal Necrolysis (TEN; a skin rash often with blisters, lesions and lifting skin) that have been reported when Sabril is taken in addition to other antiepileptic

drugs known to cause SJS and TEN. Closely monitor for skin reactions, if symptoms or signs of SJS or TEN are present, Sabril treatment should be stopped. The best results in managing SJS and TEN come from early detection and stopping the drug treatment right away (see table of **Serious Side Effects and What to do About Them**, below).

- **Driving and using machines:** Before driving, operating complex machinery or performing other activities that require mental alertness or physical coordination, wait until you know how you or your child respond to Sabril. Treatment with Sabril can cause you/your child to feel drowsy or tired and affect your ability to perform these activities.
- **Weight gain:** Treatment with Sabril causes weight gain.
- **Do not suddenly stop taking Sabril.** Always follow your healthcare professional's instructions. Stopping this drug quickly may lead to an increase in seizure activity or rebound seizures.

**DURING treatment with Sabril, tell your healthcare professional if you/your child develops:**

- Thoughts of suicide or self-harm
- Abnormal vision (narrowing of your vision, blurry or double vision)

**Tell your healthcare professional about all the medicines you/your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with Sabril:**

- Phenytoin. When Sabril is given with phenytoin, the levels of phenytoin may decrease.

**How to take Sabril:**

It is important that you take Sabril exactly as your healthcare professional has instructed. Your healthcare professional will start with a low dose and slowly increase the dose to the lowest amount needed to control your/your child's epilepsy.

Sabril tablets and powder for oral solution (sachets) may be taken with or without food.

Do not suddenly stop taking your medicine. Discontinuation of your medicine should be done gradually over a few weeks and only in consultation with your healthcare professional. Always check that you have enough medicine and do not run out.

**Usual dose:**

*Adults:* The usual maintenance dose in adults is between 2 to 3 g/day divided into 2 doses.

*Children (2-16 years of age):* The dose is based on weight and the maintenance dose is approximately 50 mg/kg/day.

*Infants:* The dose is based on weight and the recommended dose for the management of Infantile Spasms is between 50-100 mg/kg/day.

*Elderly and Patients with Renal Impairment:* These patients should be started on a lower dose.

It is important to follow your healthcare professional's instructions exactly. Never change the

dose yourself.

Your healthcare professional will have told you how much medicine to take or give to your child. Each dose should be made up just before it is used.

If you are using powder for oral solution (sachets):

1. Open the number of sachets your healthcare professional told you to use.
2. Empty the entire contents into an empty glass.
3. Using an oral syringe measure 10 mL of liquid for each sachet used and add it to the powder. You may use cold or room temperature water, fruit juice, milk or infant formula as the liquid. Mix the liquid and the powder until the powder has dissolved completely.

Number of Sachets	Number of mL of Liquid for Dissolving
1 sachet	10 mL
2 sachets	20 mL
3 sachets	30 mL

4. Using the oral syringe, measure the exact volume of dissolved medicine your healthcare professional told you to use.
5. Take or give to your child the measured volume of dissolved medicine immediately.
6. Throw away any unused dissolved medicine immediately; do not save this medicine for the next dose.

#### **Overdose:**

If you think you have taken too much Sabril, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

#### **Missed Dose:**

If you/your child forget to take a dose, take it as soon as you remember, and then go on as usual. However, if it is almost time for your next dose, skip the forgotten dose, and go on as usual.

#### **What are possible side effects from using Sabril?**

These are not all the possible side effects you may feel when taking Sabril. If you or your child experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

The most common side effects associated with the use of Sabril are:

- Headache
- Sleepiness/drowsiness, fatigue, trouble sleeping
- Common cold, sore throat
- Weight gain

- Nausea/vomiting, diarrhea, constipation, indigestion
- Joint pain
- Rash

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b> Hyperactivity in children		√	
<b>COMMON</b> Vision problems (symptoms like blurred vision, double vision, narrowing your vision, any other vision changes)		√	
Breathing problems, cough	√		
Seizures		√	
Anemia (symptoms like fatigue, loss of energy, weakness, shortness of breath)		√	
Edema (symptoms like swelling of your legs, ankles and/or feet)		√	
Nervous system problems (symptoms like abnormal movements, memory problems, abnormal eye movements, confusion, dizziness, trouble walking or with coordination, tremor (shakiness), trouble talking, dizziness along with the feeling of a spinning movement)		√	
Nerve problems (symptoms like numbness and tingling in the feet and toes, loss of feeling)		√	
Psychiatric disorders (symptoms like depression, irritability, agitation, mood swings, restlessness, anxiety, aggressiveness, nervousness, delusions, changes in thinking, personality changes)		√	
Fever		√	
<b>UNCOMMON</b> Thoughts of suicide or self-harm			√

<b>RARE</b> Severe allergic reactions (symptoms like swelling of face, eyes, lips, or tongue, trouble swallowing or breathing, skin rash)			√
Brain disease, including swelling in the brain (symptoms like excessive sleepiness, unconsciousness and confusion)		√	
<b>VERY RARE</b> Serious Skin Reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis): Any combination of itchy skin rash, redness, blistering and peeling of the skin and/or of the lips, eyes, mouth, nasal passages, or genitals. You may also get fever, sore throat, fatigue, chills, headache, cough, body aches or joint pain.			√

If you or your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p><b>Reporting Side Effects</b></p> <p>You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.</p> <p><b>3 ways to report:</b></p> <ul style="list-style-type: none"> <li>• Online at MedEffect (<a href="http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php">http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php</a>);</li> <li>• By calling 1-866-234-2345 (toll-free);</li> <li>• By completing a Consumer Side Effect Reporting Form and sending it by: <ul style="list-style-type: none"> <li>- Fax to 1-866-678-6789 (toll-free), or</li> <li>- Mail to: Canada Vigilance Program Health Canada, Postal Locator 0701E Ottawa, ON K1A 0K9</li> </ul> </li> </ul> <p>Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<a href="http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php">http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php</a>).</p> <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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**Storage:**

Leave your tablets and sachets in their original packaging and keep them in a safe place.

Store at controlled room temperature (15°C-30°C). Protect from moisture.

If your healthcare professional decides to stop your treatment, return any leftover medicine to your pharmacist. Only keep it if your healthcare professional tells you to do so.

Keep out of reach and sight of children.

**If you want more information about Sabril:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website [www.lundbeckus.com](http://www.lundbeckus.com), or by calling Lundbeck, at: 1-800-586-2325.

This information is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

This leaflet was prepared by Lundbeck.

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For: Lundbeck, Deerfield, IL 60015, U.S.A.



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Last Revised February 9, 2021