

MEDICATION GUIDE

SABRIL® (SAY-bril)
(vigabatrin)
Tablets

SABRIL® (SAY-bril)
(vigabatrin)
Powder for oral solution

What is the most important information I should know about SABRIL?

SABRIL can cause serious side effects, including:

- **Permanent vision loss**
- **Magnetic resonance imaging (MRI) changes in babies with infantile spasms (IS)**
- **Risk of suicidal thoughts or actions**

1. **Permanent vision loss:**

SABRIL can damage the vision of anyone who takes it. Some people can have severe loss particularly to their ability to see to the side when they look straight ahead (peripheral vision). With severe vision loss, you may only be able to see things straight in front of you (sometimes called “tunnel vision”). You may also have blurry vision. If this happens, it will not get better.

- **Vision loss and use of SABRIL in adults and children 2 years and older:** Because of the risk of vision loss, SABRIL is used to treat complex partial seizures (CPS) only in people who do not respond well enough to several other medicines.

Tell your healthcare provider right away if you (or your child):

- might not be seeing as well as before starting SABRIL.
- start to trip, bump into things, or are more clumsy than usual.
- are surprised by people or things coming in front of you that seem to come out of nowhere.
- These changes can mean that you (or your child) have damage to your vision.
- It is recommended that your healthcare provider test your (or your child's) vision (including peripheral vision) and visual acuity (ability to read an eye chart) before you (or your child) start SABRIL or within 4 weeks after starting SABRIL, and at least every 3 months after that until SABRIL is stopped. It is also recommended that you (or your child) have a vision test about 3 to 6 months after SABRIL is stopped. Your vision loss may get worse after you stop taking SABRIL.
- Some people are not able to complete testing of vision. Your healthcare provider will determine if you (or your child) can be tested. If you (or your child) cannot complete vision testing, your healthcare provider may continue prescribing SABRIL, but your healthcare provider will not be able to watch for any vision loss you (or your child) may get.
- Even if your vision (or your child's vision) seems fine, it is important that you (or your child) get these regular vision tests because vision damage can happen before you (or your child) notice any changes.
- These vision tests cannot prevent the vision damage that can happen with SABRIL, but they do allow the healthcare provider to decide if you (or your child) should stop SABRIL if your vision has gotten worse.
- Vision testing may not detect vision loss before it is severe.
- If you do not have these vision tests regularly, your healthcare provider may stop prescribing SABRIL.
- If you drive and your vision is damaged by SABRIL, driving might be more dangerous, or you may not be able to drive safely at all. Talk about this with your healthcare provider.
- **Vision loss in babies:** Because of the risk of vision loss, SABRIL is used in babies 1 month to 2 years of age with infantile spasms (IS) only when you and your healthcare provider decide that the possible benefits of SABRIL are more important than the risks.
 - Parents or caregivers are not likely to recognize the symptoms of vision loss in babies until it is severe. Healthcare providers may not find vision loss in babies until it is severe.
 - It is difficult to test vision in babies, but, to the extent possible, all babies should have their vision tested before starting SABRIL or within 4 weeks after starting SABRIL, and every 3 months after that until SABRIL is stopped. Your baby should also have a vision test about 3 to 6 months after SABRIL is stopped.
 - Your baby may not be able to be tested. Your healthcare provider will determine if your baby can be tested. If your baby cannot be tested, your healthcare provider may continue prescribing SABRIL, but your healthcare provider will not be able to watch for any vision loss.

Tell your healthcare provider right away if you think that your baby is:

- not seeing as well as before taking SABRIL.
- acting differently than normal.
- Even if your baby's vision seems fine, it is important to get regular vision tests because damage can happen before your baby acts differently. Even these regular vision exams may not show the damage to your baby's vision before it is severe and permanent.

All people who take SABRIL:

- You are at risk for permanent vision loss with any amount of SABRIL.
- Your risk of vision loss may be higher the more SABRIL you take daily and the longer you take it.

- It is not possible for your healthcare provider to know when vision loss will happen. It could happen soon after starting SABRIL or any time during treatment. It may even happen after treatment has stopped.

- Because SABRIL might cause permanent vision loss, it is available to healthcare providers and patients only under a special program called the Vigabatrin Risk Evaluation and Mitigation Strategy (REMS) Program. SABRIL can only be prescribed to people who are enrolled in this program. As part of the Vigabatrin REMS Program, it is recommended that your healthcare provider test your (or your child's) vision from time to time (periodically) while you (or your child) are being treated with SABRIL, and even after you (or your child) stop treatment. Your healthcare provider will explain the details of the Vigabatrin REMS Program to you. For more information, go to www.vigabatrinREMS.com or call 1-866-244-8175.

2. Magnetic resonance imaging (MRI) changes in babies with infantile spasms:

Brain pictures taken by magnetic resonance imaging (MRI) show changes in some babies after they are given SABRIL. It is not known if these changes are harmful.

3. Risk of suicidal thoughts or actions:

Like other antiepileptic drugs, SABRIL may cause suicidal thoughts or actions in a very small number of people, about 1 in 500 people taking it. Call a healthcare provider right away if you or your child have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- new or worse depression
- feeling agitated or restless
- trouble sleeping (insomnia)
- acting aggressive, being angry, or violent
- an extreme increase in activity and talking (mania)
- attempts to commit suicide
- new or worse anxiety
- panic attacks
- new or worse irritability
- acting on dangerous impulses
- other unusual changes in behavior or mood

Suicidal thoughts or actions can be caused by things other than medicines. If you or your child have suicidal thoughts or actions, your healthcare provider may check for other causes.

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms.
- **Do not stop SABRIL without first talking to a healthcare provider.**
- Stopping SABRIL suddenly can cause serious problems. Stopping a seizure medicine suddenly can cause seizures that will not stop (status epilepticus) in people who are being treated for seizures.

What is SABRIL?

- SABRIL is a prescription medicine used along with other treatments to treat adults and children 2 years and older with complex partial seizures (CPS) if:
 - the CPS do not respond well enough to several other treatments, **and**
 - you and your healthcare provider decide the possible benefit of taking SABRIL is more important than the risk of vision loss.
 SABRIL should not be the first medicine used to treat CPS.
- SABRIL is also used to treat babies 1 month to 2 years of age who have infantile spasms (IS) if you and your healthcare provider decide the possible benefits of taking SABRIL are more important than the possible risk of vision loss.

What should I tell my healthcare provider before starting SABRIL?

If you or your child has CPS, before taking SABRIL tell your healthcare provider about all of your medical conditions, including if you or your child:

- have or had an allergic reaction to SABRIL, such as hives, itching, or trouble breathing.
- have or had any vision problems.
- have or had any kidney problems.
- have or had low red blood cell counts (anemia).
- have or had any nervous or mental illnesses, such as depression, mood problems, thoughts of suicide, or attempts at suicide.
- are breastfeeding or planning to breastfeed. SABRIL can pass into breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take SABRIL.
- are pregnant or plan to become pregnant. SABRIL can cause harm to your unborn baby. You and your healthcare provider will have to decide if you should take SABRIL while you are pregnant.

Pregnancy Registry:

If you become pregnant while taking SABRIL, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. Information on the

registry can also be found at the website <http://www.aedpregnancyregistry.org/>. The purpose of this registry is to collect information about the safety of antiepileptic medicine during pregnancy.

If you are a parent or caregiver whose baby has IS, before giving SABRIL to your baby, tell your healthcare provider about all of your baby's medical conditions, including if your baby has or ever had:

- an allergic reaction to SABRIL, such as hives, itching, or trouble breathing.
- any vision problems.
- any kidney problems.

Tell your healthcare provider about all the medicines you or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SABRIL and other medicines may affect each other causing side effects.

How should I take SABRIL?

- SABRIL comes as tablets or powder for oral solution.
- You or your child will receive SABRIL from a specialty pharmacy.
- Take SABRIL exactly as your healthcare provider tells you to. SABRIL is usually taken 2 times each day.
- SABRIL may be taken with or without food.
- Before starting to take SABRIL, talk to your healthcare provider about what you or your child should do if a SABRIL dose is missed.
- If you or your child are taking SABRIL for CPS and the seizures do not improve enough within 3 months, your healthcare provider will stop prescribing SABRIL.
- If your child is taking SABRIL for IS and the seizures do not improve within 2 to 4 weeks, your healthcare provider will stop prescribing SABRIL.
- **Do not stop taking SABRIL suddenly.** This can cause serious problems. Stopping SABRIL or any seizure medicine suddenly can cause seizures that will not stop (status epilepticus) in people who are being treated for seizures. You should follow your healthcare provider's instructions on how to stop taking SABRIL.
- **Tell your healthcare provider right away about any increase in seizures when SABRIL treatment is being stopped.** Before your child starts taking SABRIL, speak to your child's healthcare provider about what to do if your baby misses a dose, vomits, spits up, or only takes part of the dose of SABRIL.
- **Do not stop taking SABRIL without talking to your healthcare provider.** If SABRIL improves your (or your child's) seizures, you and your healthcare provider should talk about whether the benefit of taking SABRIL is more important than the risk of vision loss, and decide if you (or your child) will continue to take SABRIL.
- If you are giving SABRIL powder for oral solution to your child, it can be given at the same time as their meal. **SABRIL for oral solution powder should be mixed with water only.**
- **See "Instructions for Use" for detailed information about how to mix and give SABRIL powder for oral solution to your child the right way.**

What should I avoid while taking SABRIL?

SABRIL causes sleepiness and tiredness. Adults taking SABRIL should not drive, operate machinery, or perform any hazardous task, unless you and your healthcare provider have decided that you can do these things safely.

What are the possible side effects of SABRIL?

SABRIL can cause serious side effects, including:

- See "[What is the most important information I should know about SABRIL?](#)"
- **sleepiness and tiredness.** See "What should I avoid while taking SABRIL?"
- **SABRIL may cause your baby to be sleepy.** Sleepy babies may have a harder time suckling and feeding, or may be irritable.
- **weight gain that happens without swelling.**

The following serious side effects happen in **adults**. It is not known if these side effects also happen in babies who take SABRIL.

- **low red blood cell counts (anemia).**
- **nerve problems.** Symptoms of a nerve problem can include numbness and tingling in your toes or feet. It is not known if nerve problems will go away after you stop taking SABRIL.
- **swelling.**

If you or your child has CPS, SABRIL may make certain types of seizures worse. Tell your healthcare provider right away if your (or your child's) seizures get worse.

The most common side effects of SABRIL in **adults** include blurred vision, sleepiness, dizziness, problems walking or feeling uncoordinated, shaking (tremor), and tiredness.

The most common side effect of SABRIL in **children 3 to 16 years of age** is weight gain. Also expect side effects like those seen in adults.

If you are giving SABRIL to your baby for IS:

SABRIL may make certain types of seizures worse. You should tell your baby's healthcare provider right away if your baby's seizures get worse. Tell your baby's healthcare provider if you see any changes in your baby's behavior.

The most common side effects of SABRIL in **babies** include:

- sleepiness - SABRIL may cause your baby to be sleepy. Sleepy babies may have a harder time suckling and feeding or may be irritable.
- ear infection
- swelling in the bronchial tubes (bronchitis)
- irritability

Tell your healthcare provider if you or your child have any side effect that bothers you or that does not go away. These are not all the possible side effects of SABRIL.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SABRIL?

- Store SABRIL tablets and SABRIL packets at room temperature between 68°F to 77°F (20°C to 25°C).

Keep SABRIL and all medicines out of the reach of children.

General information about the safe and effective use of SABRIL.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about SABRIL that is written for health professionals. Do not use SABRIL for a condition for which it was not prescribed. Do not give SABRIL to other people, even if they have the same symptoms that you have. It may harm them.

What are the ingredients in SABRIL?

Active Ingredient: vigabatrin

Inactive Ingredients:

- **Tablets:** hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycols, povidone, sodium starch glycolate, and titanium dioxide
- **Powder for oral solution:** povidone

Marketed by: Lundbeck, Deerfield, IL 60015, U.S.A. SABRIL is a registered trademark of Lundbeck

For more information, go to www.SABRIL.net or call 1-866-402-8520.



This Medication Guide has been approved by the U.S. Food and Drug Administration

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