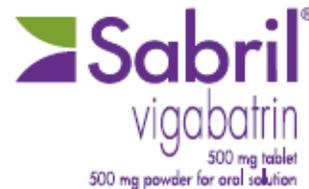


What You Need to Know About SABRIL Treatment: A Patient Guide



Patients/Caregivers: Before beginning SABRIL therapy, your Healthcare Provider will go over the risks associated with SABRIL and provide this Patient Guide to you. It is very important that you read this and ask any questions you might have about SABRIL before or during your or your child's treatment. Keep this guide for important safety information about serious risks involved with taking SABRIL.

Healthcare Providers: Please review the risks associated with SABRIL, including vision loss and the need for periodic monitoring with your patient and/or caregiver. Please also provide a copy of this Patient Guide for them to take home. Healthcare providers should ensure that periodic visual monitoring, as described in the Prescribing Information, is performed on an ongoing basis.

What is SABRIL?

SABRIL is a prescription medication used with other treatments in adults and children 10 years of age and older with refractory complex partial seizures (CPS), who have not responded well enough to several other treatments and for whom the potential benefits outweigh the risk of vision loss.

SABRIL is also used to treat babies 1 month to 2 years of age who have infantile spasms (IS) and for whom the potential benefits outweigh the potential risk of vision loss.

SABRIL is available only through certified healthcare providers and pharmacies.

What is the Most Serious Risk Information about SABRIL Treatment?

SABRIL can cause **permanent vision damage** to anyone who takes it. The most noticeable loss is in the ability to see to the side when looking straight ahead (peripheral vision). If this happens, it will not get better. People who take SABRIL do not lose all of their vision, but some people can have severe loss and may only be able to see things straight in front of them (sometimes called "tunnel vision"), and they may also have blurry vision.

You are at risk for vision loss with any amount of SABRIL. 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.

Your healthcare provider will discuss periodic vision monitoring with you. Even if your or your child's vision seems fine, it is important that regular vision tests are done 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 vision has gotten worse, which usually will lessen further damage.

What are the Signs of Vision Loss with SABRIL Treatment?

Symptoms of vision loss from SABRIL are unlikely to be recognized by patients or caregivers before it is severe.

Tell your healthcare provider right away if you or your child notice any of the following signs as these changes can mean that vision damage has occurred:

- Loss is in the ability to see to the side when looking straight ahead (peripheral vision).
- Blurry vision.
- Not 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.
- If your baby is acting differently than normal.

These are **NOT** all the possible side effects of SABRIL. Refer to the SABRIL Medication Guide that will be given to you when you receive your prescription and talk to your healthcare provider for medical advice about other side effects.

What Can I Do to Help Reduce the Risk of Vision Loss with SABRIL?

- Before starting treatment with SABRIL, discuss how often vision testing should be done with your or your child's healthcare provider. Regular visits to an ophthalmologist or optometrist may help you decide if/when you or your child should stop SABRIL, but it will not prevent vision loss.
 - Visit an ophthalmologist or optometrist as recommended by your healthcare provider. Report any changes in your or your child's vision to your doctor as soon as possible.
 - 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; or if your baby is acting differently than normal.
-

How Often Will I or My Child Take SABRIL?

- A child with Infantile Spasms will be given SABRIL two times a day.
- A child ages 10 to 16 with refractory complex partial seizures will start therapy at 250 mg twice a day. The dose may increase to 1000 mg twice a day according to healthcare provider instructions*.
- Children and adults ages 16 and older with refractory complex partial seizures will start therapy at 500 mg twice a day. The dose may increase to 1500 mg twice a day according to healthcare provider instructions.

*For refractory CPS patients ages 10 to 16, the dosage is based on body weight. Patients weighing more than 60 kg (132lbs.) should be dosed according to adult recommendations.

Where Can I Get More Information on SABRIL?

You should receive a SABRIL Medication Guide with each prescription. You can also find more information at www.SabriREMS.com or call the SABRIL REMS Program at the toll-free number **1-888-457-4273**.

©2016 Lundbeck. All rights reserved. SABRIL is a registered trademark of Lundbeck. VGB-L-00016