

# SABRIL PRESCRIPTION FORM

## Patient Authorization and Information

Name (First, Middle, Last): \_\_\_\_\_ Sex:  Male  Female DOB: \_\_\_\_\_  
Month/Day/Year

Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP Code: \_\_\_\_\_

SSN: \_\_\_\_\_ Phone: \_\_\_\_\_ Today's Date: \_\_\_\_\_  
Last 4 Digits Month/Day/Year

Sabril Administration Site:  Home  Hospital

## Patient Authorization for Use and Disclosure of Personal Health Information

I authorize my healthcare providers (including pharmacy providers) and health plans to disclose my personal health information related to this prescription form or my use or potential use of SABRIL, including my personal contact information on this form (collectively, my "Information"), to the patient support program called the **SHAREPlus** Program (the "Program") so that the Program may use and disclose the Information in order to: (1) establish my benefit eligibility; (2) communicate with my healthcare providers and health plans about my benefit and coverage status and my medical care; (3) provide support services, including facilitating the provision of SABRIL to me, as well as any information or materials related to such services or Lundbeck products, including promotional or educational communications; (4) evaluate the effectiveness of SABRIL support programs; (5) report safety information, including in communications with the US Food and Drug Administration and other government authorities; (6) contact me regarding this prescription form or my use or potential use of SABRIL and provide me with related patient support communications, including through messages left for me that disclose that I take or may take SABRIL; and (7) allow Lundbeck to analyze the usage patterns and the effectiveness of Lundbeck products, services, and programs and help develop new products, services, and programs, and for other Lundbeck general business and administrative purposes.

I understand that my pharmacy provider(s) may receive remuneration in exchange for the provision of my Information as authorized above, and that once my Information has been disclosed to the Program, federal privacy law may no longer restrict its use or disclosure and that it may be redisclosed to others. I also understand, however, that the Program plans to use and disclose my Information only for the purposes described above or as required by law.

I understand that if I refuse to sign this Authorization, that will not affect my right to treatment or payment of benefits for health care. I also understand that if I sign, I may later withdraw this Authorization by sending written notice of my withdrawal from the Program to the **SHAREPlus** Coordinating Center at PO Box 10526, Gaithersburg, MD 20898, and that such withdrawal will not affect any uses and disclosures of my Information prior to the Program's receipt of the notice. I am entitled to a copy of this signed Authorization, which expires 10 years from the date it is signed by me or such timeframe as allowed by law.

Patient/Parent/Legal Guardian Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Month/Day/Year

Power of Attorney:  Yes  No  N/A Power of Attorney (First, Middle, Last): \_\_\_\_\_

**Please see Important Safety Information, including Boxed Warning for risk of permanent vision loss, on page 4. For more information, please see Sabril [full Prescribing Information](#), [Medication Guide](#), and [Instructions for Use](#); or go to [www.Sabril.net](http://www.Sabril.net).**

## Patient Insurance Information

Primary Insurance Plan: \_\_\_\_\_ Plan Phone Number: \_\_\_\_\_

Group Number: \_\_\_\_\_ ID Number: \_\_\_\_\_

Cardholder Name: \_\_\_\_\_ Plan Number: \_\_\_\_\_

Relationship to Cardholder:  Self  Spouse  Child  Other

Primary Insurance Plan is associated with:  Medicaid  CHIP  Medicare  TRICARE  Veterans programs

Other government programs\*

Secondary Insurance Plan: \_\_\_\_\_ Plan Phone Number: \_\_\_\_\_

Group Number: \_\_\_\_\_ ID Number: \_\_\_\_\_

Cardholder Name: \_\_\_\_\_ Plan Number: \_\_\_\_\_

Relationship to Cardholder:  Self  Spouse  Child  Other

Secondary Insurance Plan is associated with:  Medicaid  CHIP  Medicare  TRICARE  Veterans programs

Other government programs\*

Prescription Benefit Manager: \_\_\_\_\_ Phone Number: \_\_\_\_\_

Cardholder Name: \_\_\_\_\_ Plan Number: \_\_\_\_\_

Group Number: \_\_\_\_\_ ID Number: \_\_\_\_\_

\*The Federal Employees Health Benefits Program and plans offered through state or federal exchanges established by the Affordable Care Act are not considered "government programs" for purposes of this form.

## Prescriber Information and Attestation

Prescriber's Name (First, Middle Initial, Last): \_\_\_\_\_ NPI #: \_\_\_\_\_

Prescriber Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP Code: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

Prescriber State License Number: \_\_\_\_\_

**Prescriber Certification and Authorization:** I certify that, to the full extent required by applicable law, I have obtained written permission from my patient named above (or from the patient's legal representative) to release to the patient support program, the **SHAREPlus** Program ("the Program"), the patient's personal health information, both as provided on this form and such other personal health information as the Program may need (1) to perform a preliminary verification of the patient's insurance coverage for SABRIL, (2) to assess the patient's eligibility for participation in the Program, (3) to enroll the patient in the Program, (4) to provide reimbursement support and other services to the patient in connection with the patient's prescription(s) on this form, and (5) for the other purposes identified on the Sabril Patient Authorization and Information Form. I authorize and appoint the Program to convey on my behalf any prescription information delivered to the Program through this form to the dispensing pharmacy chosen by or for the patient. I agree that the Program may contact me for additional information relating to the Program, SABRIL, or the prescription(s) contained on this form, including but not limited to via e-mail, fax, and telephone.

I understand that any Sabril provided at no charge to the patient is provided on a complimentary basis. I will not submit or cause to be submitted any claims for payment or reimbursement for such products to any third-party payor, including a federal health care program. If I am or become in possession of such product, I will not resell or attempt to resell and will return the product to **SHAREPlus**.

Name of Prescriber: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Month/Day/Year

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This prescription is filled by SHAREPlus.

**This prescription will allow eligible patients access to Sabril while Sabril benefits investigation is ongoing (a limited supply may be provided during this time). This prescription will be filled for eligible patients by SHAREPlus. The prescription in the green box below will be forwarded by SHAREPlus to a certified pharmacy for fulfillment.**

Prescription: Sabril  500-mg tablets  500-mg powder for oral solution\* (up to 30 days): \_\_\_\_\_

Quantity

\*Child Weight (kg): \_\_\_\_\_ Date: \_\_\_\_\_ Refills: \_\_\_\_\_  
Month/Day/Year Quantity

**Sabril Prescribing Information suggested dosing:**

- **For adults (patients 17 years of age and older):** Treatment should be initiated at 1000 mg/day (500 mg twice daily). Total daily dose may be increased in 500-mg/day increments at weekly intervals, depending on response. The recommended dose of Sabril in adults is 3000 mg/day (1500 mg twice daily)
- **For patients 10 to 16 years of age:** Treatment for patients weighing 25 kg to 60 kg should be initiated at a total daily dose of 500 mg/day (250 mg twice daily) and may be increased weekly in 500-mg/day increments to a total maintenance dose of 2000 mg/day (1000 mg twice daily). Patients weighing more than 60 kg should be dosed according to adult recommendations
- **For infants (1 month to 2 years of age):** The initial daily dosing is 50 mg/kg/day given in 2 divided doses (25 mg/kg twice daily); subsequent dosing can be titrated by 25-mg/kg/day to 50-mg/kg/day increments every 3 days, up to a maximum of 150 mg/kg/day given in 2 divided doses (75 mg/kg twice daily)

SIG<sup>†</sup>: \_\_\_\_\_  
<sup>†</sup>Write directions for use in the SIG section.

Primary ICD-10 Code: \_\_\_\_\_ Secondary ICD-10 Code: \_\_\_\_\_

Instructions: Ship to:  Patient home (address given under Patient Information on page 1)  Other (address below)

Patient Name: \_\_\_\_\_ Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP Code: \_\_\_\_\_ Phone: \_\_\_\_\_

**Prescriber's Signature** (Sign either line **A** or **B** below.) (Physician attests this is his/her legal signature. **NO STAMPS**)



A. DISPENSE AS WRITTEN <sup>‡</sup>	DATE	B. PRODUCT SUBSTITUTION PERMITTED	DATE
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<sup>‡</sup>Certain states require "brand medically necessary" to be handwritten by the prescriber if he/she has made this determination in his/her independent clinical judgment.

**Notes:** The prescriber should comply with state-specific prescription requirements. Noncompliance could result in outreach to the prescriber. All **SHAREPlus** terms and conditions apply.

This prescription is filled by the certified pharmacy.

**Prescription for fulfillment by certified pharmacy. Up to a 12-month supply may be provided.**

Prescription: Sabril  500-mg tablets  500-mg powder for oral solution\* (up to 12 months): \_\_\_\_\_

Quantity

\*Child Weight (kg): \_\_\_\_\_ Date: \_\_\_\_\_ Refills: \_\_\_\_\_  
Month/Day/Year Quantity

**Sabril Prescribing Information suggested dosing:**

- **For adults (patients 17 years of age and older):** Treatment should be initiated at 1000 mg/day (500 mg twice daily). Total daily dose may be increased in 500-mg/day increments at weekly intervals, depending on response. The recommended dose of Sabril in adults is 3000 mg/day (1500 mg twice daily)
- **For patients 10 to 16 years of age:** Treatment for patients weighing 25 kg to 60 kg should be initiated at a total daily dose of 500 mg/day (250 mg twice daily) and may be increased weekly in 500-mg/day increments to a total maintenance dose of 2000 mg/day (1000 mg twice daily). Patients weighing more than 60 kg should be dosed according to adult recommendations
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Primary ICD-10 Code: \_\_\_\_\_ Secondary ICD-10 Code: \_\_\_\_\_

Instructions: Ship to:  Patient home (address given under Patient Information on page 1)  Other (address below)

Patient Name: \_\_\_\_\_ Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ ZIP Code: \_\_\_\_\_ Phone: \_\_\_\_\_

**Prescriber's Signature** (Sign either line **A** or **B** below.) (Physician attests this is his/her legal signature. **NO STAMPS**)



A. DISPENSE AS WRITTEN <sup>‡</sup>	DATE	B. PRODUCT SUBSTITUTION PERMITTED	DATE
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**Notes:** The prescriber should comply with state-specific prescription requirements. Noncompliance could result in outreach to the prescriber. All **SHAREPlus** terms and conditions apply.

**Please see Important Safety Information, including Boxed Warning for risk of permanent vision loss, on page 4. For more information, please see Sabril [full Prescribing Information](#), [Medication Guide](#), and [Instructions for Use](#); or go to [www.Sabril.net](http://www.Sabril.net).**



Your Partner in Epilepsy™

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## SABRIL® (vigabatrin) tablets, for oral use SABRIL® (vigabatrin) powder for oral solution

### Indications and Usage

SABRIL (vigabatrin) is indicated as adjunctive therapy for patients 10 years of age and older with refractory complex partial seizures (CPS) who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. SABRIL is not indicated as a first line agent for CPS.

SABRIL (vigabatrin) is indicated as monotherapy for pediatric patients 1 month to 2 years of age with infantile spasms (IS) for whom the potential benefits outweigh the potential risk of vision loss.

### Important Safety Information

#### **WARNING: PERMANENT VISION LOSS**

*See full Prescribing Information for complete boxed warning.*

- SABRIL can cause permanent bilateral concentric visual field constriction, including tunnel vision that can result in disability. In some cases, SABRIL may also reduce visual acuity.
- Risk increases with increasing dose and cumulative exposure, but there is no dose or exposure to SABRIL known to be free of risk of vision loss.
- Risk of new and worsening vision loss continues as long as SABRIL is used, and possibly after discontinuing SABRIL.
- Baseline and periodic vision assessment is recommended for patients on SABRIL. However, this assessment cannot always prevent vision damage.
- SABRIL is available only through a restricted program called the Vigabatrin REMS Program.

- SABRIL can cause permanent bilateral concentric visual field constriction, including tunnel vision that can result in disability. SABRIL also can damage the central retina and may decrease visual acuity.
- Risk of new or worsening vision loss continues as long as SABRIL is used, and is not reversible. The onset of vision loss is unpredictable and can occur soon after starting treatment, at any time during treatment, even after months or years, or possibly after discontinuation. Symptoms of vision loss from SABRIL are unlikely to be recognized by patients or caregivers before it is severe. Vision loss of milder severity may still adversely affect function.
- Vision assessment is recommended at baseline (no later than 4 weeks after starting SABRIL), at least every 3 months during therapy, and 3 to 6 months after discontinuing therapy. Even with frequent monitoring, some patients will develop severe vision loss. Consider drug discontinuation, balancing benefit and risk, if vision loss is documented.
- Because of the risk of permanent vision loss, withdraw SABRIL from patients with refractory complex partial seizures who fail to show substantial clinical benefit within 3 months of initiation, and from patients with infantile spasms within 2 to 4 weeks of initiation, or sooner, if treatment failure becomes obvious. Periodically reassess patient response and continued need for SABRIL.
- Do not use SABRIL in patients with, or at high risk of, other types of irreversible vision loss, or, with other drugs associated with serious adverse ophthalmic effects, unless the benefits clearly outweigh the risks.
- Use the lowest dosage and shortest exposure to SABRIL that is consistent with clinical objectives. Adjust the dose in patients with renal impairment.
- Abnormal magnetic resonance imaging (MRI) signal changes have been observed in some infants treated for IS with SABRIL. These changes generally resolved with discontinuation of treatment, and resolved in a few patients despite continued use.
- Antiepileptic drugs (AEDs), including SABRIL, increase the risk of suicidal thoughts and behavior. Monitor patients for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.
- As with all AEDs, discontinue SABRIL gradually to avoid withdrawal seizures. However, if withdrawal is needed because of a serious adverse event, rapid discontinuation can be considered.
- SABRIL can cause anemia, peripheral neuropathy, weight gain, and edema. SABRIL can cause somnolence and fatigue. Advise patients not to drive or operate machinery until they know how SABRIL will affect them.
- Do not use SABRIL during pregnancy unless the potential benefit justifies the potential risk to the fetus. **Pregnancy Registry:** To provide information regarding the effects of *in utero* exposure to SABRIL, physicians should recommend that pregnant patients taking SABRIL enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry. Patients must call the toll-free number 1-888-233-2334 to enroll. Registry information can be found at <http://www.aedpregnancyregistry.org/>.
- Vigabatrin is excreted in human milk and may cause serious adverse events in nursing infants. Discontinue nursing or discontinue SABRIL, taking into account the importance of the drug to the mother.
- The most common adverse reactions in controlled studies ( $\geq 5\%$  over placebo) include:
  - Adults >16 years of age with CPS: fatigue, somnolence, nystagmus, tremor, blurred vision, memory impairment, weight gain, arthralgia, abnormal coordination, and confusional state
  - Pediatrics 10 to 16 years of age with CPS: weight gain, upper respiratory tract infection, tremor, fatigue, aggression, and diplopia
  - Infants with IS: somnolence, bronchitis, ear infection, and acute otitis media

Please see SABRIL full Prescribing Information including Boxed Warning for risk of permanent vision loss, Medication Guide, and Instructions for Use; or go to [www.Sabril.net](http://www.Sabril.net).



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