SABRIL PRESCRIPTION FORM

(Note: This form is effective as of January 2022)

Sabril® vigabatrin 500 mg tablet 500 mg for oral solution

Patient Authorization and Information

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

Address: _____ City: _____ State: _____ ZIP Code: _____

Phone: _____ Today's Date: _____
Month/Day/Year

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 **SHARE*Plus*** 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 **SHARE*Plus*** Coordinating Center at PO Box 220267, Charlotte, NC 28222, 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 Indication and Important Safety Information, including Boxed Warning for risk of permanent vision loss, on pages 4-5 of this document.

Lundbeck

Fax all 3 completed pages to: **1-877-742-1002**

Patient Insurance Information

Does patient have insurance? ☐ Yes ☐ No

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 **SHARE*Plus*** 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 Patient Authorization for Use and Disclosure of Personal Health Information. I authorize and appoint the Program to convey on my behalf the prescriptions I signed for the patient and the other information included on this form to the dispensing pharmacy chosen by or for the patient. I agree that the Program may contact me, including without limitation via email, fax, and telephone, to seek additional information relating to the Program, SABRIL, or the prescription(s) contained on this form.

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 the product.

Name of Prescriber: _____ Signature: _____ Date: _____
Month/Day/Year

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This prescription is filled by **SHARE*Plus***.

This "Starter Rx" prescription is only available to new, eligible, commercially insured patients, ages 1 month to 2 years, who have been prescribed Sabril, with a diagnosis of infantile spasms. To receive the Starter Rx, "DISPENSE AS WRITTEN (DAW)" must be indicated on the prescription.* This prescription may allow eligible patients access to Sabril while Sabril benefits investigation is ongoing. Up to a 30-day one-time supply may be provided. This prescription will be filled for eligible patients by SHAREPlus. The prescription below will be forwarded by SHAREPlus to a certified pharmacy for fulfillment. Complete Terms and Conditions for the Starter Rx Program are available at www.Sabril.net.

Prescription: SABRIL ☐ 500-mg tablets ☐ 500-mg for oral solution (up to 30 days): _____
Quantity

Child Weight (kg): _____ Date: _____
Month/Day/Year

SABRIL Prescribing Information suggested dosing:

- **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[†] _____

[†]Write directions for use in the SIG section.

Primary ICD-11 Code: _____ Secondary ICD-11 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* **DATE**	**B. PRODUCT SUBSTITUTION PERMITTED** **DATE**

* Certain states require "brand medically necessary" or other language 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 **SHARE*Plus*** 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 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 2 to 16 years of age:** Treatment for patients weighing 10 kg to 60 kg should be initiated based on body weight, administered as two divided doses, and may be increased in weekly intervals to the total daily maintenance dosage, depending on response (see PI for full details). 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[†] _____

[†]Write directions for use in the SIG section.

Primary ICD-11 Code: _____ Secondary ICD-11 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* **DATE**	**B. PRODUCT SUBSTITUTION PERMITTED** **DATE**

* Certain states require "brand medically necessary" or other language 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 **SHARE*Plus*** terms and conditions apply.

Please see Indication and Important Safety Information, including Boxed Warning for risk of permanent vision loss, on pages 4-5 of this document.

Fax all 3 completed pages to: **1-877-742-1002**

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

Indications and Usage

SABRIL (vigabatrin) is indicated as adjunctive therapy for patients 2 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 decrease 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 are 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. Vision loss may get worse after stopping SABRIL. 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.

Please see additional Important Safety Information, including Boxed Warning for risk of permanent vision loss, on page 5 of this document.

- Intramyelinic edema (IME) has been reported in postmortem examination of infants being treated for IS with vigabatrin.
- Abnormal magnetic resonance imaging (MRI) signal changes have also been observed in some infants treated with SABRIL. These changes generally resolved with discontinuation of treatment and resolved in a few patients despite continued use. The specific pattern of signal changes observed in patients 6 years and younger was not observed in older pediatric and adult patients treated with vigabatrin.
- 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. The effects of SABRIL on the breastfed infant and on milk production are unknown. Because of the potential for serious adverse reactions from vigabatrin in nursing infants, breastfeeding is not recommended. If exposing a breastfed infant to SABRIL, observe for any potential adverse effects.
- The most common adverse reactions in controlled studies (≥5% over placebo) include:
  - Adults >16 years of age with refractory CPS: blurred vision, somnolence, dizziness, abnormal coordination, tremor, and fatigue
  - Pediatrics 3 to 16 years of age with refractory CPS: weight gain
    Safety of SABRIL for the treatment of refractory CPS in patients 2 years of age is expected to be similar to pediatric patients 3 to 16 years of age.
  - Infants with IS: somnolence, bronchitis, ear infection, acute otitis media, and irritability

For more information, 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.

Fax all 3 completed pages to: **1-877-742-1002**