NDA 020427/S-005 & NDA 022006/S-006
FDA approved REMS modifications 12/2012

Sabril® vigabatrin
500 mg tablet
500 mg powder for oral solution

S·H·A·R·E®
Support, Help And Resources for Epilepsy

PATIENT/PARENT/LEGAL GUARDIAN–PHYSICIAN AGREEMENT FOR SABRIL® (VIGABATRIN) USE

Completed form must be faxed to the SHARE Call Center (1-877-742-1002) at treatment initiation. Place the original signed document in the patient's medical record and provide a copy to the patient, parent, or legal guardian.

Identification of Signer:

Patient—I, _____, am the patient. I am able to read and understand this document and will sign for myself.

OR

Parent/Legal Guardian—I am not the patient. I am the parent/legal guardian of _____, who is the patient. I am able to read and understand this document and will sign on behalf of the patient.

To use Sabril appropriately, the patient/parent/legal guardian should:

- **Be aware that Sabril causes a serious vision problem in some people.**
- **Be aware that there have been reports of changes in the brain images of some patients with infantile spasms on Sabril. The importance of these changes is not known.**
- **Read the *Medication Guide* to understand the risks of Sabril therapy.**
- **Talk with the doctor about the information you receive before signing the *Patient/Parent/Legal Guardian-Physician Agreement*.**
- **Report any problems you/your infant might experience when using Sabril to the doctor as soon as they happen.**
- **Visit the doctor regularly to make sure that Sabril continues to be right for you/your infant to take.**

This agreement is to be completed and signed by the patient/parent/legal guardian and the doctor. The person who signs is to read each item below and, if every item is understood, your signature goes at the end of this agreement. Do not sign this agreement, or take Sabril yourself, or give Sabril to your infant, if there are any unanswered questions.

1. I, _____, have read the *Sabril Medication Guide*. The doctor has explained the risks.

2. I understand that Sabril is a medicine used to treat infantile spasms, or complex partial seizures that have not responded to several other treatments. The doctor and I have talked about treatment choices and have decided that treatment with Sabril is appropriate.

3. I understand that about 1 in 3 patients taking Sabril has vision damage. I understand that if any vision loss occurs, it will not improve even if Sabril is stopped.

4. I understand that there is no way to tell if vision loss will develop.

5. I understand that the doctor may order periodic vision assessments when starting Sabril treatment, while Sabril is being taken, and after stopping therapy. I understand that these tests will not prevent vision loss. However, by stopping the treatment as a result of these tests, the amount of vision loss may be limited. I understand that it is important to see the doctor on a regular basis to make sure that Sabril continues to be appropriate.

6. I understand that there have been reports of a change in the brain pictures of infants taking Sabril. The change may reverse by itself or when the Sabril dose is lowered or is stopped. It is not known if this change has any effect on the infant.

7. I understand that my infant's doctor may want to take an MRI or picture of my infant's brain before starting or during Sabril® (vigabatrin) treatment.

8. The doctor and I have talked about my/my infant's epilepsy. We have also talked about the potential benefits and risks of taking Sabril. We have agreed that Sabril therapy will be started, and that the initial treatment with Sabril will consist of an Evaluation Phase of about 3 months for adults taking Sabril for CPS and about 1 month for infants taking Sabril for IS.

9. If the seizures are not better during the Evaluation Phase, Sabril therapy must be stopped. If seizure control has improved, I will discuss with the doctor the potential benefits and risks of continuing Sabril therapy (the Maintenance Phase). I understand that the risk of vision loss will continue as long as Sabril is taken.

10. I understand that Sabril will be prescribed for myself, my son or daughter, or my legal ward only. I will not share Sabril with other people.

11. The doctor has discussed with me other treatments for my/my infant's epilepsy. We have decided that Sabril is the right treatment. I understand that Sabril can be discontinued at any time. I also know that I/my infant cannot stop taking Sabril without the doctor telling me to do so. I agree to tell the doctor if a decision is made to stop taking Sabril. I understand that if my infant's treatment is abruptly stopped, my infant's seizures might increase or return.

12. All my questions were answered to my satisfaction. I now authorize the doctor, _____, to begin my/my infant's treatment with Sabril.

I have read and understood all of the information presented above and agree to use Sabril therapy.

Patient/Parent/Legal Guardian Agreement

To be signed by patient/parent/legal guardian upon initiation of Sabril therapy.

Signature: _____ Date: _____
month/day/year

Patient Name: _____ Telephone: _____
Area Code Telephone Number

Patient Address: _____
Street City State ZIP

Physician Agreement

I, _____, have fully explained to the patient/parent/legal guardian the potential benefits and risks of Sabril treatment. I have provided the patient/parent/legal guardian with the brochure entitled *Sabril Medication Guide* and have answered all questions regarding therapy with Sabril.

To be signed by physician upon initiation of Sabril therapy.

Signature: _____ Date: _____
month/day/year

Fax to the SHARE Call Center (1-877-742-1002)

Lundbeck Inc., Deerfield, IL 60015.