For real-time processing of the Vigabatrin REMS Program Patient/Parent/Legal Guardian–Physician Agreement Form, go to www.vigabatrinREMS.com to enroll online. To submit this form via fax, please complete all required fields below and fax both pages to the Vigabatrin REMS Program at 1-866-205-3072.

Vigabatrin is available only through a restricted distribution Risk Evaluation and Mitigation Strategy (REMS) program called the Vigabatrin REMS Program. The Vigabatrin REMS Program is available to answer questions regarding this program and initiating treatment with vigabatrin. Please call 1-866-244-8175 for assistance.

To the Physician:
Completed forms must be submitted to the Vigabatrin REMS Program prior to treatment initiation. Place the original signed document in the patient’s medical record and provide a copy to the patient, parent, or legal guardian.

For the Patient or Parent/Legal Guardian:
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 the parent/legal guardian of ____________________________, who is the patient. I am able to read and understand this document and will sign it where appropriate on behalf of the patient.

To use vigabatrin appropriately, the patient/parent/legal guardian should:
• Be aware that vigabatrin can cause serious vision problems in some people
• Be provided and have read What You Need to Know About Vigabatrin Treatment: A Patient Guide
• Be counseled by the prescriber regarding the risks associated with vigabatrin, including permanent vision loss
• Be counseled by the prescriber regarding the need for periodic monitoring of vision, including ophthalmologic assessments, based on the recommendations in the Prescribing Information
• Report to the doctor any problems you or your child might experience when using vigabatrin as soon as they happen
• Visit the doctor regularly to make sure that taking vigabatrin continues to be right for you/your child to take

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

I, ____________________________, have been provided and have read What You Need to Know About Vigabatrin Treatment: A Patient Guide. The doctor has explained the risk of permanent vision loss, as well as the need for periodic vision testing and the recommended times that the tests should be done.

Prescriber NPI# ________________ Form continues on page 2.
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1. The doctor and I have talked about my/my child’s epilepsy. We have also talked about the potential benefits and risks of taking vigabatrin.

2. I understand that vigabatrin will be prescribed for me or my child only. I will not share vigabatrin with other people.

3. The doctor has discussed with me other treatments for my/my child’s epilepsy. We have decided that vigabatrin is the right treatment. I understand that vigabatrin can be discontinued at any time. I also know that I/my child cannot stop taking vigabatrin without the doctor telling me to do so.

4. I agree to tell the doctor if a decision is made to stop taking vigabatrin. I understand that if my/my child’s treatment is abruptly stopped, my/my child’s seizures might increase or return.

5. All my questions were answered to my satisfaction. I now authorize the doctor, ______________________________, to begin my/my child’s treatment with vigabatrin.

I have read and understood all of the information presented above and agree to use vigabatrin therapy and agree to participate in the Vigabatrin REMS Program.

Patient/Parent/Legal Guardian Agreement

To be signed by patient/parent/legal guardian when starting of vigabatrin therapy.

*Signature__________________________________________  *Date_________________________

Month/Day/Year

*Patient Name________________________________________ Telephone______________________

Area Code/Telephone Number

Patient/Parent/Legal Guardian Email Address __________________________________________

Patient Address

Street________________________________________ City____________ State________ ZIP Code

*Patient Date of Birth______________________________

Month/Day/Year

*Physician Agreement

I, ________________________________ , have fully explained to the patient/parent/legal guardian the potential benefits and risks of vigabatrin treatment, including permanent vision loss and the need for periodic vision monitoring. I have provided the patient/parent/legal guardian with the document, What You Need to Know About Vigabatrin Treatment: A Patient Guide, and have answered all questions regarding therapy with vigabatrin. Upon completion of this agreement form, I will store a copy of the form in the patient’s record and will provide the patient/parent/legal guardian a copy of the form.

To be signed by physician upon initiation of vigabatrin therapy.

*Signature__________________________________________  *Date_________________________

Month/Day/Year

To report Adverse Events, please contact the Vigabatrin REMS Program at 1-866-244-8175.

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