

**UPSHER-SMITH**

*Partners in Health Since 1919*

**Contact:** Elizabeth Likly  
Kovak-Likly Communications  
203-762-8833, elikly@klcpr.com

**FOR IMMEDIATE RELEASE**

## **UPSHER-SMITH LAUNCHES VIGABATRIN FOR ORAL SOLUTION UNDER THE BRAND NAME VIGADRONE™**

*Offers Patients and Physicians a Fully Substitutable Generic Alternative with Brand-Quality Support*

Maple Grove, MN – July 16, 2018 – [Upsher-Smith Laboratories, LLC](#) (Upsher-Smith) today announced the launch of [Vigadrone™ \(vigabatrin\) for Oral Solution, 500 mg](#), a fully substitutable, AA-rated generic version of Sabril® (vigabatrin) powder for oral solution.\* The product was approved by the U.S. Food and Drug Administration (FDA) on June 21, 2018. The Vigabatrin powder market had U.S. sales of approximately \$333 million for the 12 months ending December 31, 2017 according to IQVIA. Upsher-Smith partnered with Aucta Pharmaceuticals, LLC for product development and manufacturing.



**Vigadrone™ (vigabatrin) for Oral Solution, 500 mg.  
Upsher-Smith Laboratories, LLC**

Vigadrone™ is indicated for the treatment of:

- Infantile Spasms (IS)—monotherapy in infants 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.
- Refractory Complex Partial Seizures (CPS)—adjunctive therapy in patients ≥10 years of age who have responded inadequately to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss; Vigadrone™ is not indicated as a first line agent.

**Please see Important Safety Information, including Boxed Warning for Risk of Permanent Vision Loss at the end of this communication.**

Vigadrone™ is supported by Upsher-Smith's Access Pathways® Program, which is designed to reduce the barriers associated with prescribing vigabatrin by providing brand-quality support to physicians, patients, and caregivers. The Access Pathways® Program includes:

- Benefit verification

- If the patient is covered, a starter prescription will be shipped to the patient or caregiver and the prescription will be processed by a specialty pharmacy partner.
- Prior authorization support<sup>†</sup>
  - If the patient requires a prior authorization, the Access Pathways<sup>®</sup> support team will contact their insurance provider and get the process going, as well as follow up with the physician, patient or caregiver to confirm the prior authorization is complete. The patient will be provided with a bridge supply while the prior authorization is completed.
- A cash option is available if the patient is not covered or uninsured
- Co-Pay assistance for eligible patients\*\*

To learn more about Access Pathways<sup>®</sup>, visit [vigadrone.com](http://vigadrone.com). Access Pathways<sup>®</sup> Program Support can be reached:

<b>Monday – Friday:</b> 8am – 9pm EST	<b>Phone:</b> 1-866-923-1954	<b>Fax prescription forms:</b> 1-877-788-4948
<b>Weekends:</b> Friday 9pm – Sunday 9pm EST	<b>Phone:</b> 1-866-923-1954	<b>Fax prescription forms:</b> 1-877-788-4942

“At Upsher-Smith, we understand that physicians want to begin treating infantile spasms quickly upon diagnosis,” said Rusty Field, President and CEO of Upsher-Smith. “We are supporting Vigadrone<sup>™</sup> with our Access Pathways<sup>®</sup> Program to help ensure that physicians will be able to start their patients on Vigadrone<sup>™</sup> as quickly, and as seamlessly, as possible.”

### **Vigabatrin REMS Program**

The U.S. FDA has approved a single shared system Risk Evaluation and Mitigation Strategy (REMS) for all vigabatrin products called the Vigabatrin REMS Program. It is required by the FDA to ensure informed risk-benefit decisions before initiating treatment and to ensure appropriate use of vigabatrin while patients are treated.

Healthcare providers must be certified in the Vigabatrin REMS Program to prescribe Vigadrone<sup>™</sup> and patients must be enrolled in the Vigabatrin REMS Program to receive Vigadrone<sup>™</sup>. All certified prescribers and enrolled patients in the SABRIL<sup>®</sup> REMS Program have been transitioned to the Vigabatrin REMS Program and **do not** need to recertify or re-enroll.

## WHAT IMPORTANT SAFETY INFORMATION SHOULD I KNOW ABOUT VIGADRONE?

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

***See Medication Guide and full Prescribing Information for complete information.***

#### **All people who take VIGADRONE:**

- You are at risk for permanent vision loss with any amount of VIGADRONE.
- Your risk of vision loss may be higher the more VIGADRONE you take daily and the longer you take it.
- It is not possible for your healthcare provider to know when vision loss will happen. It could happen soon after starting VIGADRONE or any time during treatment. It may even happen after treatment has stopped.

- **Because VIGADRONE might cause permanent vision loss, it is available to healthcare providers and patients only under a special program called the Vigabatrin Risk Evaluation and Mitigation Strategy (REMS) Program. Your healthcare provider will explain the details of this Program to you.**
- **VIGADRONE can damage the vision of anyone who takes it.** People who take VIGADRONE do not lose all of their vision, but some people can have severe loss, particularly their peripheral vision. With **severe vision loss**, you may have "tunnel vision". You may also have **blurry vision**. If this happens, it will not get better.
- **Tell your healthcare provider right away if you (or your child):** might not be seeing as well as before starting VIGADRONE; 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. **These changes can mean that vision damage has occurred.**
- **Regular vision testing is recommended.** It is recommended that your healthcare provider test your (or your child's) vision before, during, and after treatment with VIGADRONE. **Regular vision testing is important because damage can happen before any changes are noticed.**
- **Vision tests cannot prevent the vision damage** that can happen with VIGADRONE, but they do allow VIGADRONE to be stopped if vision has gotten worse. Even these regular vision tests may not show vision damage before it is serious and permanent. **Parents, caregivers, and healthcare providers may not recognize the symptoms, or find vision loss in babies, until it is severe.**
- **If you do not have these vision tests, your healthcare provider may stop prescribing VIGADRONE for you (or your child). Some people are not able to complete vision testing. If vision testing cannot be done, your healthcare provider may continue prescribing VIGADRONE, but will not be able to watch for any vision loss.**
- **Magnetic resonance imaging (MRI) changes in babies with IS.** Brain pictures taken by MRI show changes in some babies after they are given VIGADRONE. It is not known if these changes are harmful.

- **Risk of suicidal thoughts or actions.** Like other antiepileptic drugs, VIGADRONE may cause suicidal thoughts and actions in some people (about 1 in 500 people). Call a healthcare provider right away if you experience these effects, or any symptoms of depression or mood changes.
- **Do not stop VIGADRONE without first talking to a healthcare provider.** Stopping VIGADRONE suddenly can cause seizures that will not stop.

**VIGADRONE can cause serious side effects** such as low red blood cell counts (anemia), sleepiness and tiredness, nerve problems, weight gain, and swelling. Because VIGADRONE causes sleepiness and tiredness, do not drive, operate machinery, or perform any hazardous task, unless it is decided that these things can be done safely. VIGADRONE may make certain types of seizures worse. **Tell your healthcare provider right away if seizures get worse.**

**Before starting VIGADRONE, tell your doctor about all of your (or your child's) medical conditions,** including mental illnesses, and all the medicines you (or your child) take.

**If you are breastfeeding or plan to breastfeed, VIGADRONE can pass into breast milk and may harm your baby.**

**If you are pregnant or plan to become pregnant,** it is not known if VIGADRONE will harm your unborn baby. You and your healthcare provider will have to decide if you should take VIGADRONE while you are pregnant.

**The most common side effects of VIGADRONE in adults include:** problems walking or feeling uncoordinated, feeling dizzy, shaking (tremor), joint pain, memory problems and not thinking clearly, and eye problems like blurry vision, double vision, and eye movements that cannot be controlled.

**The most common side effects of VIGADRONE in children 10 to 16 years of age** include weight gain, upper respiratory tract infection, tiredness, and aggression. Also expect side effects like those seen in adults.

**The most common side effects of VIGADRONE in babies include:** sleepiness—some babies may have a harder time suckling and feeding or may be irritable, swelling in the bronchial tubes (bronchitis), ear infection, and irritability.

**Tell your healthcare provider if you or your child have any side effect that bothers you or that does not go away.**

**This is the most important information to know about VIGADRONE, but not all of the possible side effects of VIGADRONE.** For more information, ask your healthcare provider or pharmacist, or please visit [vigadrone.com/PI](http://vigadrone.com/PI) for VIGADRONE [Medication Guide](#), [full Prescribing Information](#) including Boxed Warning for risk of permanent vision loss, and Instructions for Use. You can also visit [upsher-smith.com](http://upsher-smith.com) or call 1-888-650-3789.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-332-1088.

## About Upsher-Smith

Upsher-Smith Laboratories, LLC is a trusted U.S. pharmaceutical company that strives to improve the health and lives of patients through an unwavering commitment to high-quality products and sustainable growth. Our diverse portfolio today includes specialty generics, which

we've been formulating and manufacturing since 1919, as well as branded prescription medications to help treat disorders such as seizures and migraine headaches.

As we approach our 100<sup>th</sup> year in business, we enter a new ambitious era that has been accelerated by our 2017 acquisition by Sawai Pharmaceutical Co., Ltd. With our new owner, we look to leverage each other for growth worldwide and embark on an exciting new chapter. Together, we seek to deliver the best value for our stakeholders, and most importantly, to do more good for the patients we serve.

For more information, visit [www.upsheer-smith.com](http://www.upsheer-smith.com).

\*Sabril is a registered trademark of Lundbeck.

\*\*Medicare, Medicaid and other state and federal health care program patients are not eligible.

†Prior authorization support can be provided only for indicated disease states.

VIGADRONE and Access Pathways are trademarks of Upsheer-Smith Laboratories, LLC.