



## Endo Begins Shipment of Generic Sabril® (vigabatrin) for Oral Solution

August 28, 2017

DUBLIN, Aug. 28, 2017 /PRNewswire/ -- Endo International plc (NASDAQ: ENDP) announced today that one of its operating companies, Par Pharmaceutical, has begun shipping vigabatrin for oral solution USP, 500 mg per packet following final approval from the U.S. Food and Drug Administration for its Abbreviated New Drug Application. Par's vigabatrin for oral solution is the generic version of Lundbeck LLC's Sabril® and is the first and currently the only generic version available. Vigabatrin is available only through certified healthcare providers and specialty pharmacies.

"We are pleased to be able to offer patients a cost-effective option to Sabril®," said Tony Pera, President of Par Pharmaceutical. "Par's vigabatrin for oral solution is therapeutically equivalent to the brand and is therefore substitutable. We are proud to continue our tradition at Par of providing high quality, affordable medicines."

According to IMS Health data, U.S. sales of Sabril® for oral solution were approximately \$329M for the 12 months ended June 2017.

Sabril® is a registered trademark of Lundbeck.

### **About Endo International plc**

Endo International plc (NASDAQ: ENDP) is a highly focused generics and specialty branded pharmaceutical company delivering quality medicines to patients in need through excellence in development, manufacturing and commercialization. Endo has global headquarters in Dublin, Ireland, and U.S. headquarters in Malvern, PA. Learn more at [www.endo.com](http://www.endo.com).

### **About Par Pharmaceutical**

Par Pharmaceutical, headquartered in Chestnut Ridge, NY, develops, manufactures and markets safe, innovative and cost-effective generic pharmaceutical products that help improve patient quality of life. Par, among the top four leaders in the U.S. generics industry, possesses a portfolio that includes sterile injectables, alternative dosage forms and many other differentiated products. Par is advancing a research and development (R&D) pipeline of more than 200 potential new products. Par is an operating company of Endo International plc. Learn more at [www.endo.com](http://www.endo.com) or [www.parpharm.com](http://www.parpharm.com).

### **Cautionary Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements, including the statements by Mr. Pera, within the meaning of the Private Securities Litigation Reform Act of 1995 and Canadian securities legislation. Because these statements reflect Endo's current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties. Although Endo believes that these forward-looking statements and information are based upon reasonable assumptions and expectations, readers should not place undue reliance on them, or any other forward-looking statements or information in this news release. Investors should note that many factors, as more fully described in the documents filed by Endo with the Securities and Exchange Commission ("SEC") and with securities regulators in Canada on the System for Electronic Document Analysis and Retrieval ("SEDAR), and as otherwise enumerated herein or therein, could affect Endo's future financial results and could cause Endo's actual results to differ materially from those expressed in this communication. The forward-looking statements in this press release are qualified by these risk factors. Endo does not assume any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise, except as may be required under applicable securities laws.

### **Important Safety Information**

#### **Vigabatrin for oral solution – Consumer Indication and Important Safety Information**

##### **What is vigabatrin for oral solution?**

Vigabatrin for oral solution is a prescription medicine used with other treatments in adults and children 10 years of age and older with refractory complex partial seizures (CPS) who have not responded well enough to several other treatments and if the possible benefits outweigh the risk of vision loss. Vigabatrin should not be the first medicine used to treat CPS.

Vigabatrin is a prescription medicine used in babies, 1 month to 2 years old, with infantile spasms, if the possible benefits outweigh the possible risk of vision loss.

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

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

All people who take vigabatrin for oral solution:

- You are at risk for permanent vision loss with any amount of vigabatrin for oral solution.
- Your risk of vision loss may be higher the more vigabatrin for oral solution 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 vigabatrin for oral solution or any time during treatment. It may even happen after treatment has stopped.

**IMPORTANT SAFETY INFORMATION about vigabatrin for oral solution**

- Because vigabatrin for oral solution 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. Vigabatrin for oral solution can only be prescribed to people who are enrolled in this program. Your healthcare provider will explain the details of this program to you.

- **Vigabatrin for oral solution can damage the vision of anyone who takes it. People who take vigabatrin for oral solution do not lose all of their vision, but some people can have severe loss particularly to their ability to see to the side when looking straight ahead (peripheral vision). With severe vision loss, you may only be able to see things straight in front of you (sometimes called "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 vigabatrin for oral solution; 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.**
- **It is recommended that your healthcare provider test your (or your child's) vision before or within 4 weeks after starting vigabatrin for oral solution, and at least every 3 months during treatment until vigabatrin for oral solution is stopped. It is also recommended that vision be tested about 3 to 6 months after vigabatrin for oral solution is stopped. It is difficult to test vision in babies, but to the extent possible, all babies should have their vision tested. Your healthcare provider will determine if testing can be done. 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 vigabatrin for oral solution, but they do allow vigabatrin for oral solution to be stopped if vision has gotten worse, which usually will lessen further damage. Even these regular vision tests may not show vision damage before it is serious and permanent. Once detected, vision loss is not reversible. Parents, caregivers, and healthcare providers may not recognize the symptoms, or find vision loss in babies, until it is severe. Less severe vision loss can still negatively affect function.**
- **If vision tests are not done regularly, your healthcare provider may stop prescribing vigabatrin for oral solution 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 vigabatrin for oral solution, but will not be able to watch for any vision loss.**
- Brain pictures taken by magnetic resonance imaging (MRI) show changes in some babies after they are given vigabatrin for oral solution. It is not known if these changes are harmful.
- Like other antiepileptic drugs, vigabatrin for oral solution may cause suicidal thoughts and actions in some people. Call a healthcare provider right away if you (or your child) have any of these symptoms: thoughts about suicide or dying, new or worse depression, feeling agitated or restless, trouble sleeping (insomnia), acting aggressive, being angry, or violent, an extreme increase in activity and talking (mania), attempts to commit suicide, new or worse anxiety, panic attacks, new or worse irritability, acting on dangerous impulses, other unusual changes in behavior or mood; and especially if they are new, worse, or worry you.
- Do not stop vigabatrin without first talking to a healthcare provider. Stopping vigabatrin for oral solution suddenly can cause seizures that will not stop in people who are being treated for seizures.
- Vigabatrin for oral solution can cause serious side effects such as low red blood cell counts (anemia), sleepiness and tiredness, nerve problems, weight gain, and swelling. Because vigabatrin for oral solution 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. Vigabatrin for oral solution may make certain types of seizures worse. Tell your healthcare provider right away if seizures get worse.
- Before starting vigabatrin for oral solution, tell your doctor about all of your (or your child's) medical conditions, including depression, mood problems, suicidal thoughts or behavior, any allergic reaction to vigabatrin for oral solution, vision problems, kidney problems, low red blood cell counts (anemia), and any nervous or mental illness. Tell your doctor about all the medicines you (or your child) take.
- If you are breastfeeding or plan to breastfeed, vigabatrin for oral solution can pass into breast milk and may harm your baby. If you are pregnant or plan to become pregnant, it is not known if vigabatrin for oral solution will harm your unborn baby. You and your healthcare provider will have to decide if you should take vigabatrin for oral solution while you are pregnant.
- The most common side effects of vigabatrin for oral solution 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 vigabatrin for oral solution 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 vigabatrin for oral solution 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. These are not all of the possible side effects of vigabatrin for oral solution. For more information, ask your healthcare provider or pharmacist.

**Please see the full Prescribing Information, including Boxed Warning and Medication Guide at [vigabatrin.com/assets/pdfs/VIGABATRIN\\_PI.pdf](http://vigabatrin.com/assets/pdfs/VIGABATRIN_PI.pdf).**

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.

View original content: <http://www.prnewswire.com/news-releases/endo-begins-shipment-of-generic-sabril-vigabatrin-for-oral-solution-300509806.html>

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