



## **Press Release**

### **Granules India Limited announces approval of Vigabatrin for Oral Solution USP, 500 mg**

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#### **Hyderabad, April 27, 2020**

Granules India Limited announced today that the US Food & Drug Administration (US FDA) has approved the Abbreviated New Drug Application (ANDA) filed by Granules Pharmaceuticals, Inc. (GPI), a wholly owned foreign subsidiary of Granules India Limited for Vigabatrin for Oral Solution USP, 500 mg. It is bioequivalent to the reference listed drug product (RLD), Sabril® (vigabatrin) for Oral Solution, 500 mg, of Lundbeck Pharmaceuticals LLC.

Vigabatrin for Oral Solution is indicated as adjunctive therapy for adults and pediatric patients 2 years of age and older with refractory complex partial seizures who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. Vigabatrin for Oral Solution is not indicated as a first line agent for complex partial seizures.

Vigabatrin for Oral Solution is also indicated as monotherapy for pediatric patients with infantile spasms 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

“We are delighted to announce approval of our first specialty product, which also happens to be our first product approved in sachet (for oral solution) dosage form. It reiterates our strategy and capability for delivering diversified product portfolio in the US market. We are happy to see two ANDA approvals within one week” said Priyanka Chigurupati, Executive Director, Granules Pharmaceuticals, Inc., commenting on the approval.

Vigabatrin for Oral Solution (brand and generic) products had U.S. sales of approximately \$255 million MAT for the most recent twelve months ending in February 2020 according to IQVIA Health.

Granules now has a total of 27 ANDA approvals from US FDA (25 Final approvals and 2 tentative approvals).

*The Granules generic product received FDA approval under a Risk Evaluation and Mitigation Strategy (REMS) known as the Vigabatrin REMS program. Information on this program is available at <https://www.vigabatrinrems.com/> or +1 866-244-8175. See full prescribing information for complete boxed warning.*

Sabril® is a registered trademark of Lundbeck



## **About Granules India Ltd. (BSE: 532482, NSE: GRANULES)**

Granules India is a growing pharmaceutical manufacturing company with best in class facilities and is committed to operational excellence, quality and customer service. The Company produces Finished Dosages (FDs), Pharmaceutical Formulation Intermediates (PFIs) and Active Pharmaceutical Ingredients (APIs) which gives the customers flexibility and choice. Granules support customers with unique value, extensive product range, and proactive solutions. The Company's global presence extends to over 250 customers in 60 countries through offices in India, U.S., and U.K. The Company has 6 manufacturing facilities out of which 5 are located in India and 1 in USA and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, K FDA, DEA, MCC and HALAL.

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### ***Safe Harbour***

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