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Dr. Reddy's Laboratories announces the re-launch of Zenatane® (Isotretinoin Capsules, USP), 10 mg, 20 mg, 30 mg and 40 mg in the U.S. Market

Hyderabad, India, June 3, 2019

For Immediate Release

Hyderabad, India and Princeton, NJ, USA. June 3, 2019 — Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, along with its subsidiaries together referred to as "Dr. Reddy's") today announced the re-launch of Zenatane® (Isotretinoin Capsules, USP), 10 mg, 20 mg, 30 mg and 40 mg a therapeutic equivalent generic version of Accutane®, approved by the U.S. Food and Drug Administration (USFDA). The product is being launched with an approved Risk Evaluation and Mitigation Strategy (REMS) Program.

"We're pleased to bring this important product back to market for the customers and patients who will benefit from access to this medicine and who have had witnessed limited supply and options in the market place," explains Marc Kikuchi, Chief Executive Officer, North America Generics. "Furthermore, this is important for our company as we have commercialized the first Softgel dosage product from Dr. Reddy's own manufacturing plant to ensure consistent and robust supply for this product in the U.S. market."

The Zenatane (Isotretinoin Capsules, USP), 10 mg, 20 mg, 30 mg and 40 mg brand and generic had U.S. sales of approximately \$525 million MAT for the most recent twelve months ending in March 2019 according to IQVIA Health*.

Dr. Reddy's Zenatane (Isotretinoin Capsules, USP) are available in 3x10 (30-count) blister packages of 10 mg, 20 mg 30 mg, and 40 mg Capsules, USP.

CONTRAINDICATIONS AND WARNINGS

Zenatane must not be used by patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking Zenatane in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

Birth defects which have been documented following Zenatane exposure include abnormalities of the face, eyes, ears, skull, central nervous system, cardiovascular system, and thymus and parathyroid glands. Cases of IQ scores less than 85 with or without other abnormalities have been reported. There is an increased risk of spontaneous abortion, and premature births have been reported.

Documented external abnormalities include: skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphism; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit); cardiovascular abnormalities; thymus gland abnormality; parathyroid hormone deficiency. In some cases death has occurred with certain of the abnormalities previously noted.

If pregnancy does occur during treatment of a female patient who is taking Zenatane, Zenatane must be discontinued immediately and she should be referred to an Obstetrician- Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Special Prescribing Requirements

Because of Zenatane's teratogenicity and to minimize fetal exposure, Zenatane is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE™. Zenatane must only be prescribed by prescribers who are registered and activated with the iPLEDGE program. Zenatane must only be dispensed by a pharmacy registered and activated with iPLEDGE, and must only be dispensed to patients who are registered and meet all the requirements of iPLEDGE.

Accutane® is a trademark of Hoffman LaRoche

*IQVIA Retail and Non-Retail MAT March 2019
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About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses - Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products – Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Dr. Reddy's operates in markets across the globe. Our major markets include – USA, India, Russia & CIS countries, and Europe. For more information, log on to: www.drreddys.com
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The company assumes no obligation to update any information contained herein.