

Dr. Reddy's announces the re-launch of Zenatane

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The product is being launched with an approved Risk Evaluation and Mitigation Strategy (REMS) Program



Dr. Reddy's Laboratories has announced the relaunch 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.

Marc Kikuchi, Chief Executive Officer, North America Generics said, "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. 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.