

Dr. Reddy's launches generic Daraprim in US market

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Dr. Reddy's Laboratories has announced the launch of Pyrimethamine Tablets USP, 25 mg, a therapeutic equivalent and first-wave generic version of Daraprim[®] (pyrimethamine) Tablets, approved by the U.S. Food and Drug Administration (USFDA). This product is the only AB-rated generic version Daraprim[®] (pyrimethamine) Tablets approved by the USFDA.

"I am extremely proud of our teams at Dr. Reddy's and Cerovene whose hard work and efforts, coupled with significant financial investments over the past seven years journey, have helped bring this important product to market," says, Marc Kikuchi, Chief Executive Officer, North America Generics, Dr.Reddy's Laboratories. "Our team's relentless pursuit of this difficult-to-procure reference drug and its active pharmaceutical ingredients—in addition to recent actions from the USFDA — will benefit patients by providing a more affordable alternative to the brand." According to Kikuchi, the company is offering this product at a substantial discount compared with the current brand price.

"The achievements of the Cerovene team to develop, file and manufacture Pyrimethamine Tablets is a testament to our dedication and commitment to be able to provide this product to the patients who need it most. We are pleased to collaborate with Dr. Reddy's as our commercial partner to make this important drug available to patients in the U.S.," says, Ray DiFalco, Co-Founder and Vice President of Operations for Cerovene. "This approval represents our continued commitment to develop and provide patients with greater choices and lower-cost alternatives for prescription pharmaceuticals."

In a recent press release regarding the approval of this product, the USFDA reiterated its commitment to improve "the efficiency of the generic drug development, review and approval process, as well as closing loopholes that allow brand-name drug companies to delay the generic competition." The approval and launch of Dr. Reddy's Pyrimethamine is a testament to the agency's actions, providing generic drug companies the opportunity to compete fairly in the marketplace.

Pyrimethamine is indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide, since synergism exists with this combination. The Daraprim[®] (pyrimethamine) brand had U.S. sales of approximately \$10 million MAT for the most recent twelve months ending in January 2020 according to IQVIA Health*. Dr. Reddy's Pyrimethamine Tablets USP, are available in 25 mg dose in bottle count sizes of 30 and 100.