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## Dr. Reddy's Laboratories announces the launch of Pyrimethamine Tablets USP, 25 mg, first-wave generic version of Daraprim® in the U.S. Market

Hyderabad, India, March 20, 2020

For Immediate Release

Hyderabad, India and Princeton, NJ, USA. March 20, 2020—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 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.

### Important Safety Information

#### What Important Information Should I Know About Pyrimethamine Tablets USP, 25 mg?

- At the first appearance of a skin rash, stop use of Pyrimethamine and seek medical attention immediately
- Appearance of sore throat, paleness, purpura, or changes to the tongue may be early indications of serious disorders which require treatment with Pyrimethamine to be stopped and medical treatment to be sought

- Pyrimethamine should be kept out of the reach of infants and children as they are extremely susceptible to adverse effects from an overdose.
- Take your medicine as directed and do not exceed recommended doses
- If anorexia and vomiting occur, then they may be minimized by taking the drug with meals
- Concurrent administration of folinic acid is strongly recommended with treatment of toxoplasmosis in all patients
- If signs of folate deficiency develop, then Pyrimethamine should be discontinued

### **Who Should Not Use Pyrimethamine Tablets USP, 25 mg?**

- Have known hypersensitivity to Pyrimethamine or to any component of the formulation
- Have documented megaloblastic anemia due to folate deficiency

### **What Should I Tell My Healthcare Provider Before Taking Pyrimethamine Tablets USP, 25 mg?**

Before taking Pyrimethamine Tablets, tell your doctor if you:

- Have impaired renal function
- Have impaired hepatic function
- Have possible folate deficiency, such as individuals with malabsorption syndrome, alcoholism, or pregnancy, and those receiving therapy, such as phenytoin, affecting folate levels
- Take other antifolate drugs or agents associated with myelosuppression including sulfonamides or trimethoprim-sulfamethoxazole combinations, proguanil, zidovudine, or cytostatic agents (e.g., methotrexate), which may increase the risk of bone marrow suppression while concomitantly receiving Pyrimethamine
- Take lorazepam
- Have convulsive disorders
- Have heart conditions, especially irregular heartbeat
- Are pregnant or plan to become pregnant
- Are nursing or plan to breastfeed

### **What Are the Adverse Reactions of Pyrimethamine Tablets USP, 25 mg?**

Call your doctor or get emergency help right away if you develop:

- Hypersensitivity reactions, occasionally severe (such as Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, and anaphylaxis), and hyperphenylalaninemia, can occur particularly when pyrimethamine is administered concomitantly with a sulfonamide
- Megaloblastic anemia
- Leukopenia
- Thrombocytopenia
- Pancytopenia
- Neutropenia
- Atrophic glossitis
- Hematuria (Blood in urine)
- Heart rhythm disorders
- Pulmonary eosinophilia

Anorexia and vomiting may also occur.

### **What Should I Avoid While Taking Pyrimethamine Tablets USP, 25 mg?**

- Females of reproductive potential should avoid becoming pregnant during treatment
- Avoid breastfeeding while receiving Pyrimethamine

Please refer to the Package Insert for full prescribing information for Pyrimethamine Tablets USP, 25 mg. For more information, ask your healthcare provider or pharmacist. You are encouraged to report negative side effects of prescription drugs. To report suspected side effects, call Dr. Reddy's Laboratories Medical Information Hotline at 1-888-DRL-DRUG (1-888-375-3784) or via email to [medinfo@drreddys.com](mailto:medinfo@drreddys.com) or contact the USFDA at 1-800-FDA-1088 (1-800-332-1088) or online at <http://www.fda.gov/safety/medwatch>.

### **Indication and Usage for Pyrimethamine Tablets USP, 25 mg**

- Treatment of Toxoplasmosis: Pyrimethamine is indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide, since synergism exists with this combination.

Please see the full prescribing information.

[https://www.drreddys.com/pi/Pyrimethamine\\_Tabs\\_USP\\_25mg\\_PROOF.pdf](https://www.drreddys.com/pi/Pyrimethamine_Tabs_USP_25mg_PROOF.pdf)

Daraprim® is a trademark owned by or licensed to Vyera Pharmaceuticals, LLC

\*IQVIA Retail and Non-Retail MAT January 2020.

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**About Cerovene:** Cerovene, Inc., a privately held company, is engaged in the research, development and manufacturing of pharmaceuticals. The company's expertise in both solid and liquid dosage products, extends across a range of drug delivery technologies, including Pulse Release, Delayed and Sustained Release, Extended Release, Sustained Zero-Order Release, Matrix-Hydrogel Controlled Release, Enteric Coated, Tablet in Capsule and Coated Capsules. Cerovene develops, files and manufactures both Branded and Generic pharmaceutical products. For more information visit [www.cerovene.com](http://www.cerovene.com)

**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](http://www.drreddys.com)

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The company assumes no obligation to update any information contained herein.