

PRESS RELEASE

Indoco receives Approval for Febuxostat Tablets from USFDA

December 31, 2019, Mumbai: Indoco Remedies received final approval of its ANDA for Febuxostat Tablets 40 mg and 80 mg, which is therapeutically equivalent to the Reference Listed Drug (RLD), viz., Uloric Tablets 40 mg and 80 mg of Takeda Pharmaceuticals U.S.A., Inc.

The market size of Febuxostat Tablets in USA is over USD 500 million.

Febuxostat is used for the treatment of gout caused by excessive levels of uric acid in the blood (Hyperuricemia). Febuxostat prevents the production of uric acid by blocking the activity of the enzyme (xanthine oxidase) that converts purines to uric acid. Uric acid forms crystals in joints and tissues, causing inflammation and pain. Hyperuricemia can cause kidney disease and kidney stones as well.

Commenting on this achievement, **Ms. Aditi Kare Panandikar, Managing Director - Indoco Remedies Ltd. said**, "Receipt of ANDA approval for Febuxostat Tablets for the US market is very encouraging and has added another feather to Indoco's cap."

About Indoco Remedies Limited:

Indoco Remedies Ltd., headquartered in Mumbai, is a fully integrated, research-oriented pharma Company with presence in 55 countries. Indoco, a USD 140 million Company, employs over 6000 people including more than 300 skilled scientists.

The Company has 9 manufacturing facilities, 6 of which are for FDFs and 3 for APIs, supported by a state-of-the-art R&D Centre and a CRO facility. The facilities have been approved by USFDA, UK-MHRA, TGA-Australia, PMDA-Japan, etc. Indoco develops and manufactures a wide range of pharmaceutical products for the Indian and international markets. It generates more than 70 million prescriptions annually from around 3,10,000 doctors belonging to various specialties. Indoco has 9 domestic marketing divisions with a strong brand portfolio in various therapeutic segments including Respiratory, Anti-Infective, Dental Care, Pain Management, Gastro-intestinal, Ophthalmic, Cardiovascular, Anti-Diabetics, Anti-Obesity, etc. Top Indoco brands include Cyclopam, Febrex Plus, Sensodent-K, Oxipod, Cital, ATM, Cloben-G, Sensoform, Sensodent-KF, Karvol Plus, Glychek, Kidodent, Carmicide, Bactogard, etc. On the international front, Indoco has tie-ups with large generic companies like Watson (Actavis) – USA and ASPEN-South Africa.

For more details on Indoco, you may visit www.indoco.com

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