



PRESS RELEASE

Indoco Remedies receives final ANDA approval from USFDA for Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg and 20 mg

Mumbai, August 13, 2025: Indoco Remedies Ltd. announced final approval of the Company's Abbreviated New Drug Application (ANDA) for Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg and 20 mg, to market a generic equivalent to the reference listed drug (RLD), Xarelto Tablets, 2.5 mg, 10 mg, 15 mg and 20 mg, of Janssen Pharmaceuticals, Inc. (Janssen), from USFDA.

Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg and 20 mg are bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Xarelto Tablets, 2.5 mg, 10 mg, 15 mg and 20 mg, of Janssen Pharmaceuticals, Inc. (Janssen).

Rivaroxaban Tablets USP, will be manufactured by Indoco Remedies Limited, at their manufacturing facility located at L-14, Verna Industrial Area, Verna, Goa – 403722 in India.

Rivaroxaban is used for the treatment of venous thromboembolism (VTE).

Commenting on the achievement, **Ms. Aditi Panandikar, Managing Director** said, "Besides reflecting the capability of Indoco Remedies to deliver products of high-quality standards, this development also provides impetus to our growth aspirations in an important market such as the US."

About Indoco Remedies Limited:

Indoco is a fully integrated, research-oriented pharmaceutical company with a strong global presence. The Company's turnover is US\$ 180 million with a human capital of over 6000 employees, including over 400 skilled scientists and field staff who are the strength of the organization.

The Company has 11 manufacturing facilities, 7 for FDFs and 4 for APIs, supported by a state-of-the-art R&D Centre and a CRO facility. The facilities have been approved by most of the Regulatory Authorities including USFDA and UK-MHRA. Indoco develops and manufactures a wide range of pharmaceutical products for the Indian and international markets. It generates more than 106 million prescriptions annually from over 2,40,000 doctors belonging to various specialties. Indoco has 10 domestic marketing divisions, a strong brand portfolio in various therapeutic segments including Gastro-intestinal, Respiratory, Anti-Infectives, Stomatologicals, Ophthalmic, Nutritionals, Cardiovascular, Anti-Diabetics, Pain Management, Gynaecology, etc. Top Indoco brands include Cyclopam, Febrex Plus, Sensodent-K, Karvol Plus, ATM, Oxipod, Cital, Sensoform, Sensodent-KF, Aloja, Glychek, Kidodent, Subital, Rexitin, MCBM 69, Methycal, Dropizin, Noxa, Homide, Cal-Aid, Ninaf, Cital-Ui, Otores, etc. On the international front, Indoco has tie-ups with large generic companies across the globe.

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

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