

Press Release

Indoco Remedies receives final ANDA approval from USFDA for Lacosamide Oral Solution USP, 10 mg/mL

Published : January 30, 2026

Ref: Indoco Remedies

Mumbai, January 30, 2026: Indoco Remedies Ltd. announced final approval of the Company's Abbreviated New Drug Application (ANDA) for Lacosamide Oral Solution USP, 10 mg/mL, to market a generic equivalent to the reference listed drug (RLD), Vimpat Oral Solution, 10 mg/mL, of UCB, Inc. (UCB), from USFDA.

Lacosamide Oral Solution USP, 10 mg/mL, is bioequivalent and therapeutically equivalent to the reference listed drug, Vimpat Oral Solution, 10 mg/mL, of UCB, Inc. (UCB).

This product, Lacosamide Oral Solution USP, will be manufactured by Indoco Remedies Limited, at their manufacturing facility located at L-14, Verna Industrial Area, Verna, Goa – 403722 in India.

Lacosamide Oral solution is used to treat partial onset seizures and primary generalized tonic-clonic seizures in adults and children with epilepsy who are at least 4 years old.

Commenting on the achievement, Ms. Aditi Panandikar, Managing Director said, "We are excited about the ANDA approval for Lacosamide Oral Solution USP, 10 mg/mL. This approval further reinforces our commitment to delivering high-quality healthcare to patients worldwide."

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 Cyclopm, 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-Uti, Otorex, 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

For Media enquiries please contact:

Corporate Communications | +91 22 62871000

E-mail: corpcom@indoco.com