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Indoco Remedies gets USFDA nod to sell generic epilepsy medicine

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Synopsis Indoco Remedies has secured approval from the US health regulator for its generic Lacosamide oral solution. This medication is used to treat epilepsy in adults and children. The approval allows Indoco Remedies to market the drug, which is a generic version of Vimpat Oral Solution. Manufacturing will take place at their Goa facility.

New Delhi: Indoco Remedies Ltd on Friday said it has received approval from the US health regulator to market its generic version of Lacosamide oral solution used in the treatment of epilepsy.

The approval by the US Food and Drug Administration (USFDA) is for the Abbreviated New Drug Application (ANDA) for Lacosamide oral solution of strength 10 mg/ml, Indoco Remedies said in a regulatory filing.

It is a generic equivalent to reference listed drug (RLD), Vimpat Oral Solution, 10 mg/ml, of UCB, Inc, it added.

The company said the approved oral solution will be manufactured at its Verna facility in Goa.

"This approval further reinforces our commitment to delivering high-quality healthcare to patients worldwide," Indoco Remedies Managing Director Aditi Panandikar said.

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