Lupin receives USFDA nod for sleep disorder treatment tablets

According to IQVIA MAT July 2026 data, Modafinil Tablets had estimated annual sales of $70.7 million in the US market.

New Delhi: Lupin Ltd on Friday said it has received approval from the US health regulator to market Modafinil tablets used for the treatment of excessive sleepiness.

The company has received approval from the United States Food and Drug Administration (US FDA) for its Abbreviated New Drug Application (ANDA) for Modafinil Tablets USP in 100 mg and 200 mg strengths, Lupin said in a regulatory filing.

The approved product is bioequivalent to the reference listed drug (RLD), Provigil Tablets of Nuvo Pharmaceuticals (Ireland) DAC.

The medication is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea (OSA), or shift work disorder (SWD), the company said.

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Lupin currently operates 15 manufacturing facilities and maintains a presence in over 100 markets globally.

News Source:

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