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Lupin’s opoid drug gets USFDA nod

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Oxycodone hydrochloride tablets are intended for use in patients who require oral pain therapy with an opioid agonist.

Drug firm Lupin has received final approval from the United States Food and Drug Administration (USFDA) to market its Oxycodone Hydrochloride tablets USP, in the strengths of 5 mg, 10 mg, 15 mg, 20 mg and 30 mg.

The company's tablets are generic version of Mallinckrodt Inc's Roxicodone tablets.

Oxycodone hydrochloride tablets are an immediate-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain where the use of an opioid analgesic is appropriate.

Oxycodone hydrochloride tablets are intended for use in patients who require oral pain therapy with an opioid agonist. As with any opioid analgesic, it is critical to adjust the dosing regimen individually for each patient. The administration of oxycodone hydrochloride tablets, like all opioid analgesics, may obscure the diagnosis or clinical course in patients with acute abdominal conditions.

Roxicodonet tablets had US sales of USD 344 million as per IMS MAT March 2017.