

Lupin gets FDA nod for Fluoxetine Tablets USP

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Pharma major Lupin Limited (Lupin) announced that it has received approval for its Fluoxetine Tablets USP, 10 mg and 20 mg, from the United States Food and Drug Administration (FDA) to market a generic version of Eli Lilly and Company's (Eli Lilly) Prozac Tablets, 10 mg and 20 mg.

Lupin's Fluoxetine Tablets USP, 10 mg and 20 mg, is the generic version of Eli Lilly's Prozac Tablets, 10 mg and 20 mg. It is indicated in the treatment of:

- Major Depressive Disorder (MDD): Fluoxetine is indicated for the acute and maintenance treatment of Major Depressive Disorder in adult patients and in pediatric patients aged 8 to 18 years
- Obsessive Compulsive Disorder (OCD): Fluoxetine is indicated for the acute and maintenance treatment of obsessions and compulsions in adult patients and in pediatric patients aged 7 to 17 years with Obsessive Compulsive Disorder (OCD)
- Bulimia Nervosa: Fluoxetine is indicated for the acute and maintenance treatment of binge eating and vomiting behaviors in adult patients with moderate to severe Bulimia Nervosa.
- Panic Disorder: Fluoxetine is indicated for the acute treatment of Panic Disorder, with or without agoraphobia, in adult patients.

Fluoxetine Tablets, 10 mg and 20 mg, (RLD: Prozac) had annual sales of approximately USD 68.2 million in the US (IQVIA MAT December 2018).