

Lupin receives FDA approval for Fluoxetine Tablets

13 February 2019 | News

It is the generic version of Alvogen's Fluoxetine Tablets, 60mg



Pharma major Lupin announced that it has received approval for its Fluoxetine Tablets USP, 60mg, from the United States Food and Drug Administration (FDA) to market a generic version of Alvogen's Fluoxetine Tablets, 60mg.

Lupin's Fluoxetine Tablets USP, 60mg, is the generic version of Alvogen's Fluoxetine Tablets, 60mg. It is indicated in the treatment of:

Major Depressive Disorder (MDD)

Adults: Efficacy was established in one 5-week trial, three 6-week trials, and one maintenance study.

Pediatrics: Efficacy was established in two 8- to 9-week trials of patients 8 to 18 years of age.

Obsessive Compulsive Disorder (OCD)

Adults: Efficacy was established in two 13-week trials.

Pediatrics: Efficacy was established in one 13-week trial in pediatric patients 7 to 17 years of age.

Bulimia Nervosa

Adults: Efficacy was established in two 8-week trials and one 16-week trial.

Panic disorder, with or without agoraphobia

Adults: Efficacy was established in two 12-week trials.

Fluoxetine Tablets, 60mg, had annual sales of approximately USD 42.5 million in the US (IQVIA MAT December 2018).