

Lupin multiple sclerosis tablet gets tentative approval in US

Siponimod, marketed under the brand name Mayzent by Swiss giant Novartis, is indicated for the treatment of relapsing forms of multiple sclerosis (MS).



Mumbai: Lupin Limited (Lupin) today announced that its multiple sclerosis disease modifying therapy Siponimod generic tablet has received tentative approval in the US.

In a stock exchange filing the company said it received tentative approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application for Siponimod Tablets, 0.25 mg, 1 mg and 2 mg.

This product would be manufactured at Lupin's Pithampur facility in India, it added.

Siponimod, marketed under the brand name Mayzent by Swiss giant Novartis -- is indicated for treating relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease.

According to IQVIA estimates, Siponimod tablets reported total sales of \$195 million in the US over the twelve-month period ending in October this year.

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