US FDA approves Lupin's Generic Ipratropium Bromide nasal spray

The approval allows the company to market a generic version of Atrovent Nasal Spray, 0.06 per cent, manufactured by Boehringer Ingelheim Pharmaceuticals, Inc.

Mumbai: The United States Food and Drug Administration (U.S. FDA) has approved Lupin Limited's Abbreviated New Drug Application (ANDA) for Ipratropium Bromide Nasal Solution (Nasal Spray), 0.06 per cent.

The approval allows the company to market a generic version of Atrovent Nasal Spray, 0.06 per cent, manufactured by Boehringer Ingelheim Pharmaceuticals, Inc. It will be produced at Lupin's facility in Pithampur, India.

Ipratropium Bromide Nasal Solution (Nasal Spray), 0.06 per cent is indicated for symptomatic relief of rhinorrhea (runny nose) associated with the common cold or seasonal allergic rhinitis for adults and children aged 5 years and older.

According to IQVIA MAT data from November 2024, the reference drug (RLD Atrovent) had estimated annual sales of approximately USD 42 million in the U.S.

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