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Dr Reddy's receives FDA approval for nasal spray in US

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TOSYMRA is indicated for the acute treatment of migraine with or without aura in adults.

Dr. Reddy's Laboratories Ltd. and its subsidiary, Promius Pharma, LLC have announced the approval of TOSYMRA (previously known as DFN-02) by the U.S. Food and Drug Administration (FDA).

TOSYMRA is indicated for the acute treatment of migraine with or without aura in adults. TOSYMRA is the latest product to join the Promius Pharma acute migraine treatment portfolio. The company is working toward commercialization of this product.

"We are excited about the approval of TOSYMRA. This approval affirms our ability to develop well-differentiated products to meet the unmet needs of patients with migraine and HCPs treating them," said G.V. Prasad, Co-Chairman and CEO, Dr. Reddy's Laboratories.

According to Dr. Anil Namboodiripad, PhD, President, Promius Pharma, "TOSYMRA nasal spray is formulated using a proprietary novel excipient known as Intravail® to achieve blood levels similar to a 4-mg sumatriptan subcutaneous injection, resulting in rapid onset of action. Independent research shows that 26% to 40% of migraine patients are not optimally controlled with their current treatment. For patients who suffer from the debilitating and disruptive effects of migraine, there continues to be a need for reliable and efficacious treatment options. At Promius, we are committed to developing new ways of improving patient experiences. TOSYMRA is a mist-like nasal spray that acts rapidly and is well tolerated."