

Dr Reddy's migraine injection wins FDA approval

29 January 2016 | News | By BioSpectrum Bureau

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Dr Reddy's Laboratories has announced that the US Food and Drug Administration (US FDA) has approved ZEMBRACESymTouch (sumatriptan succinate) injection, a drug-device combination product intended for the treatment of acute migraine episodes, with or without aura, in adults who are inadequately managed with existing treatment regimens.

ZEMBRACESymTouch is available as a prefilled, ready-to-use, single-dose disposable auto injector containing 3 mg of sumatriptan, a selective 5-HT1B/ID receptor agonist. The injection is intended to be given subcutaneously.

"We are pleased to have received FDA approval for ZEMBRACESymTouch," said Mr Raghav Chari, executive vice president, proprietary products group at Dr Reddy's.

He added, "ZEMBRACESymTouch is the first branded product in our Neurology portfolio. Migraine affects millions of patients. Many of these patients have busy lives and quick pain relief is critical to help them manage through their daily routines. In many cases, migraine episodes are accompanied by severe nausea, making it difficult to swallow and retain pills. ZEMBRACESymTouch is specifically designed for patients who may experience certain migraine episodes and for whom a pill may not be the right option."

ZEMBRACESymtouch will be marketed in the United States by Promius Pharma, a wholly-owned specialty company of Dr Reddy's.

"This is a major milestone for the company as we continue to bring innovative medicines to patients and physicians," said Mr G V Prasad, CEO and co-chairman, Dr Reddy's.