

Tosymra™ (sumatriptan) – New drug approval

- On January 28, 2019, Dr. Reddy's Laboratories and its subsidiary, Promius Pharma announced the FDA approval of Tosymra (sumatriptan) nasal spray, for the acute treatment of migraine with or without aura in adults.
 - Tosymra should only be used if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Tosymra, reconsider the diagnosis before Tosymra is administered to treat any subsequent attacks.
 - Tosymra is not indicated for the preventive treatment of migraine.
 - Tosymra is not indicated for the treatment of cluster headache.
- Tosymra nasal spray is formulated using a proprietary novel excipient to achieve blood levels similar to a 4 mg sumatriptan subcutaneous injection.
 - Sumatriptan is also available generically as a nasal spray, injection and tablet; also available as brand Onzetra® Xsail® intranasal powder and Zembrace™ SymTouch™ autoinjector.
 - Other formulations of sumatriptan share the same indication as Tosymra. The injection is also indicated for acute treatment of cluster headache.
- The approval of Tosymra was based upon efficacy studies conducted for sumatriptan injection and on the relative bioavailability of Tosymra vs. sumatriptan subcutaneous injection (4 mg) in healthy adults.
- Tosymra is contraindicated in patients with: ischemic coronary artery disease (angina pectoris, history of myocardial infarction, or documented silent ischemia) or coronary artery vasospasm, including Prinzmetal's angina; Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders; history of stroke or transient ischemic attack or history of hemiplegic or basilar migraine because these patients are at a higher risk of stroke; peripheral vascular disease; ischemic bowel disease; uncontrolled hypertension; recent use (ie, within 24 hours) of ergotamine-containing medication, ergot-type medication, or another 5-hydroxytryptamine₁ agonist; concurrent administration of a monoamine oxidase (MAO)-A inhibitor or recent (within 2 weeks) use of an MAO-A inhibitor; hypersensitivity to sumatriptan (angioedema and anaphylaxis seen); and severe hepatic impairment.
- Warnings and precautions of Tosymra include myocardial ischemia, myocardial infarction, and Prinzmetal's angina; arrhythmias; chest, throat, neck, and/or jaw pain/tightness/pressure; cerebrovascular events; other vasospasm reactions; medication overuse headache; serotonin syndrome; increase in blood pressure; seizures; and local irritation.
- The adverse event profile for Tosymra is expected to be similar to the injection formulation of sumatriptan. In addition, an open-label study evaluated the local tolerability of repeated use of Tosymra over the course of 6 months. In this study, local irritative symptoms were reported in approximately 46% of patients treated with Tosymra, the most common of which were application site reactions (eg, burning sensations in the nose), dysgeusia, and throat irritation.
- The recommended dose of Tosymra is 10 mg given as a single spray in one nostril.
 - The maximum cumulative dose that may be given in a 24-hour period is 30 mg, with doses of Tosymra separated by at least 1 hour.
 - Tosymra may also be given at least 1 hour following a dose of another sumatriptan product.

- Dr. Reddy and Promius Pharma's launch plans for Tosymra are pending. Tosymra will be available as a single-dose nasal spray device delivering 10 mg of sumatriptan.



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