Onzeta™ Xsail™ (sumatriptan) – New Drug Approval

- On January 27, 2016, the FDA approved Avanir Pharmaceuticals’ Onzeta Xsail (sumatriptan) nasal powder, for the acute treatment of migraine with or without aura in adults.
  - Onzeta Xsail should be used only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Onzeta Xsail, reconsider the diagnosis of migraine before treatment of subsequent attacks with Onzeta Xsail.
  - Onzeta Xsail is not indicated for the prevention of migraine attacks.
  - The safety and efficacy of Onzeta Xsail have not been established for the treatment of cluster headache.
- Onzeta Xsail is an intranasal medication delivery system that administers a fast-acting dry powder formulation of sumatriptan utilizing the Xsail™ Breath Powered Delivery Device.
- The safety and efficacy of Onzeta Xsail were based on a clinical study that evaluated 212 patients randomized to Onzeta Xsail or placebo. The primary endpoint was headache relief, defined as a reduction in migraine-related pain 2 hours post treatment.
  - The percentage of patients achieving the primary endpoint was statistically significantly greater in the Onzeta Xsail group vs. the placebo group (68% vs. 45%, respectively, p < 0.05).
  - For patients with migraine associated nausea, photophobia, and phonophobia at baseline, there was a lower incidence of these symptoms at 2 hours following administration of Onzeta Xsail vs. placebo.
- Onzeta Xsail is contraindicated in patients with: ischemic coronary artery disease or coronary artery vasospasm, including Prinzmetal’s angina or in patients with other significant underlying cardiovascular disease; Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders; history of stroke, 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-hydroxytryptamine-1 (5HT-1) agonist; concurrent administration of an monoamine oxidase inhibitor (MAO-A inhibitor) or recent use (within 2 weeks) of a MAO-A inhibitor; hypersensitivity to sumatriptan; and severe hepatic impairment.
- Other warnings and precautions of Onzeta Xsail include chest, throat, neck and/or jaw pain/tightness/pressure; cerebrovascular disease; other vasospasm reactions; medication overuse headache; serotonin syndrome; increase in blood pressure; and seizures.
- The most common adverse events (≥ 2% and greater than placebo) with Onzeta Xsail use were abnormal taste, nasal discomfort, rhinorrhea, and rhinitis.
- The recommended dose of Onzeta Xsail is 22 mg administered by use of one nosepiece (11 mg) in each nostril. The patient blows forcefully through the mouthpiece to deliver sumatriptan powder into the nasal cavity.

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— The maximum dose in a 24-hour period should not exceed two doses (44 mg/4 nose pieces), or one dose of Onzetra Xsail and one dose of another sumatriptan product, separated by at least 2 hours.
— The safety of treating an average of more than 4 headaches in a 30-day period has not been established.

- Avanir Pharmaceuticals’ launch plans for Onzetra Xsail are pending. Onzetra Xsail will be available as an eight dose kit containing 8 pouches of 2 nosepieces (11 mg of sumatriptan per nosepiece) per pouch. The kit includes 2 breath-powered delivery system bodies.