RizaFilm® (rizatriptan) – New drug approval

- On April 17, 2023, IntelGenx and Gensco announced the FDA approval of RizaFilm (rizatriptan) oral film, for the acute treatment of migraine with or without aura in adults and in pediatric patients 12 to 17 years of age weighing 40 kg or more.

    - RizaFilm should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with RizaFilm, the diagnosis of migraine should be reconsidered before RizaFilm is administered to treat any subsequent attacks.
    - RizaFilm is not indicated for the preventive treatment of migraine.
    - Safety and effectiveness of RizaFilm have not been established for cluster headache.

- RizaFilm is an oral thin film formulation of rizatriptan benzoate, a serotonin (5-HT) 1B/1D receptor agonist (triptan).

    - Rizatriptan is also available generically as oral tablets and orally disintegrating tablets.
    - Other formulations of rizatriptan are indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 6 to 17 years of age.

- The efficacy of RizaFilm was based on a relative bioavailability study comparing RizaFilm 10 mg oral film to rizatriptan benzoate 10 mg tablets.

- RizaFilm is contraindicated in patients with:

    - Ischemic coronary artery disease or other significant underlying cardiovascular disease
    - 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
    - Peripheral vascular disease
    - Ischemic bowel disease
    - Uncontrolled hypertension
    - Recent use of another 5-HT_1 agonist, ergotamine-containing medication, or ergot-type medication
    - Hemiplegic or basilar migraine
    - Concurrent administration or recent discontinuation of a MAO-A inhibitor
    - Concurrent administration with propranolol
    - Hypersensitivity to rizatriptan or any of the ingredients of RizaFilm

- Warnings and precautions for RizaFilm include myocardial ischemia, myocardial infarction, and Prinzmetal's angina; arrhythmias; chest/throat/neck/jaw pain, tightness, pressure, or heaviness; cerebrovascular events; other vasospasm reactions; hypersensitivity reactions; medication overuse headache; serotonin syndrome; and increase in blood pressure.

- The most common adverse reactions in adults (≥ 5% and greater than placebo) with RizaFilm use were asthenia/fatigue, somnolence, pain/pressure sensation, dizziness, and nausea.

- The recommended dose of RizaFim in adults and pediatric patients weighing 40 kg or more is 10 mg administered on the tongue.

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  - In adults, the maximum cumulative dose that may be given in 24 hours is 30 mg, with doses separated by at least 2 hours. The safety of treating, on average, more than four headaches in a 30-day period has not been established.
  - The efficacy and safety of treatment with more than one dose of RizaFilm within 24 hours in pediatric patients 12 to 17 years of age have not been established.

- Gensco's launch plans for RizaFilm are pending. RizaFilm will be available as a 10 mg oral film.