Atzumi™ (dihydroergotamine) – New drug approval

- On April 30, 2025, Satsuma Pharmaceuticals announced the FDA approval of Atzumi (dihydroergotamine) nasal powder, for the **acute treatment of migraine with or without aura in adults**.

- Atzumi is an ergotamine derivative. Dihydroergotamine is currently available in a generic nasal spray for the same indication.

- The efficacy of Atzumi for the acute treatment of migraine with or without aura in adults was based on the relative bioavailability of Atzumi nasal powder compared to dihydroergotamine mesylate nasal spray.

- Atzumi carries a boxed warning for peripheral ischemia following coadministration with strong CYP3A4 inhibitors.

- Atzumi is contraindicated in patients:

    - With concomitant use of strong CYP3A4 inhibitors
    - With ischemic heart disease (eg, angina pectoris, history of myocardial infarction, or documented silent ischemia) or patients who have clinical symptoms or findings consistent with coronary artery vasospasm, including Prinzmetal's variant angina
    - With uncontrolled hypertension
    - With peripheral arterial disease
    - With sepsis
    - Following vascular surgery
    - With severe hepatic impairment
    - With severe renal impairment
    - With known hypersensitivity to ergot alkaloids
    - With recent use (ie, within 24 hours) of other 5-HT1 agonists or ergotamine-containing or ergot-type medications
    - With concomitant use of peripheral and central vasoconstrictors because the combination may result in additive or synergistic elevation of blood pressure.

- Warnings and precautions for Atzumi include myocardial ischemia, and/or infarction, other cardiac adverse reactions, and fatalities; cerebrovascular adverse reactions and fatalities; other vasospasm related adverse reactions; increase in blood pressure; medication overuse headache; preterm labor; fibrotic complications; and local irritation.

- The most common adverse reactions (> 1%) with Atzumi use were rhinitis, nausea, altered sense of taste, application site reactions, dizziness, vomiting, somnolence, pharyngitis, and diarrhea.

- The recommended dose of Atzumi is 5.2 mg (the contents of one nasal device) and is administered as a powdered medicine into one nostril.

    - The dose may be repeated, if needed, a minimum of 1 hour after the first dose. The maximum dose in a 24-hour period is 10.4 mg (two doses of 5.2 mg).
    - The safety of taking more than 4 doses in a 7-day period or 12 doses within a 30-day period has not been established.

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- Satsuma's launch plans for Atzumi are pending. Atzumi will be available as a 5.2 mg powder in a single-dose nasal device.