Brekiya® (dihydroergotamine) – New drug approval

- On May 15, 2025, Amneal Pharmaceuticals announced the FDA approval of Brekiya (dihydroergotamine), for the **acute treatment of migraine with or without aura and the acute treatment of cluster headaches in adults**.
    - Brekiya is not indicated for the preventive treatment of migraine.
    - Brekiya is not indicated for the management of hemiplegic migraine or migraine with brainstem aura.
- Brekiya is an ergotamine derivative. Dihydroergotamine is currently available in a generic solution for injection for the same indication.
    - Brekiya is the first autoinjector formulation of dihydroergotamine.
- Brekiya carries a boxed warning for peripheral ischemia following coadministration with strong CYP3A4 inhibitors.
- Brekiya 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 dihydroergotamine, ergot alkaloids, latex, or any of the ingredients in Brekiya
    - With recent use (ie, within 24 hours) of other 5-HT1 agonists, 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.
- Additional warnings and precautions for Brekiya 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 complication; and hypersensitivity.
- Serious cardiac events (including fatal) that have been reported with dihydroergotamine mesylate injection use include coronary artery vasospasm, transient myocardial ischemia, myocardial infarction, ventricular tachycardia, and ventricular fibrillation.
- The recommended dose of Brekiya is **1 mg administered subcutaneously via a single 1 mL autoinjector**. The dose may be repeated, as needed, at 1-hour intervals to a total maximum of 3 mg (3 doses) in a 24-hour period.
    - A total of 6 mg (6 doses) should not be exceeded in a week.

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- Amneal Pharmaceuticals plans to launch Brekiya in the second half of 2025. Brekiya will be available as a 1 mg/mL single-dose autoinjector.