Trudhesa™ (dihydroergotamine mesylate) – New drug approval

- On September 3, 2021, Impel NeuroPharma announced the FDA approval of Trudhesa (dihydroergotamine mesylate) nasal spray, for the acute treatment of migraine with or without aura in adults.

    - Trudhesa is not indicated for the preventive treatment of migraine.
    - Trudhesa is not indicated for the management of hemiplegic or basilar migraine.

- Dihydroergotamine mesylate nasal spray is also available generically and under the brand name Migranal®. This version of the product shares the same indication as Trudhesa.

- The efficacy of Trudhesa is based on the relative bioavailability of Trudhesa nasal spray compared to dihydroergotamine mesylate nasal spray in healthy subjects.

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

- Trudhesa is contraindicated in patients: with concomitant use of strong CYP3A4 inhibitors; with ischemic heart disease 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-HT_1 agonists (eg, sumatriptan) 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.

- Additional warnings and precautions for Trudhesa 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 Trudhesa use were rhinitis, nausea, altered sense of taste, application site reactions, dizziness, vomiting, somnolence, pharyngitis, and diarrhea.

- The recommended dose of Trudhesa is 1.45 mg administered as two metered sprays into the nose (one spray of 0.725 mg into each nostril). The dose may be repeated, if needed, a minimum of 1 hour after the first dose. More than 2 doses of Trudhesa should not be used within a 24-hour period or 3 doses within a 7-day period.

    - Prior to initiation of Trudhesa, a cardiovascular evaluation is recommended. For patients with risk factors predictive of coronary artery disease who are determined to have a satisfactory cardiovascular evaluation, it is strongly recommended that administration of the first dose of Trudhesa take place in the setting of an equipped healthcare facility.

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- Impel NeuroPharma plans to launch Trudhesa in early October 2021. Trudhesa will be available as a nasal spray delivering 0.725 mg dihydroergotamine mesylate per spray.

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