

Federal Employee Program.

MIGRAINE POWDERS

(Sumatriptan Powder/Zolmitriptan Powder)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

The selective serotonin receptor agonists, or "triptans", are a class of medications that have the ability to stop a migraine. Triptans work by binding to serotonin receptors in the brain. Specifically, per Drug Facts and Comparisons pharmacology of the Serotonin 5-HT₁ Receptor Agonists (Triptans): The vascular 5-HT1 receptor subtype is present on the human basilar artery and in the vasculature of isolated human dura mater. Current theories on the etiology of migraine headaches suggest that symptoms are caused by local cranial vasodilation or the release of vasoactive and proinflammatory peptides from sensory nerve endings in an activated trigeminal system. The therapeutic activity of the serotonin 5-HT1 receptor agonists in migraine most likely can be attributed to agonist effects at 5-HT1B/1D receptors on the extracerebral, intracranial blood vessels that become dilated during a migraine attack and on nerve terminals in the trigeminal system. Activation of these receptors results in cranial vessel constriction, inhibition of neuropeptide release, and reduced transmission in trigeminal pain pathways (1).

Regulatory Status

FDA-approved indication: Migraine powders are indicated for the acute treatment of migraine attacks with or without aura in adults. Migraine powders are not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of migraine powders has not been established for cluster headache in any dosage form other than injectable (2-3).

This class of medications has potentially serious side effects, especially when taken in high doses. Life-threatening disturbances of cardiac rhythm and myocardial infarction have been reported, as well as stroke. Excessive use of triptans can lead to medication overuse headache (2-3).

Off-Label Use:

Compounded topical preparations of migraine powders have not been proven to be safe or effective.

Triptans have been found to be safe and effective in the pediatric and adolescent population (4).

Summary



Federal Employee Program.

MIGRAINE POWDERS

(Sumatriptan Powder/Zolmitriptan Powder)

Migraine powders are indicated for the acute treatment of migraine attacks with or without aura in adults. Migraine powders are not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of migraine powders has not been established for cluster headache in any dosage form other than injectable. Migraine powders must be prescribed by a neurologist for ages 6-11 (1-4).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Triptan powders while maintaining optimal therapeutic outcomes.

References

- Serotonin 5-HT1 Receptor Agonists (Triptans). Drug Facts and Comparisons. Facts & Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; December 2017.
- 2. Zomig and Zomig-ZMT [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; May 2019.
- 3. Imitrex tablets [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2020.
- 4. Evers S., The Efficacy of Triptans in Childhood and Adolescence. *Migraine Curr Pain Headache Rep.* 2013;17(7):342.