Imitrex Tablets (sumatriptan succinate) - Drug Summary

GlaxoSmithKline LLC

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Imitrex
(sumatriptan)

THERAPEUTIC CLASS

5-$HT_{1B/1D}$ agonist (triptans)

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Cluster Headache

Inj:
Max Single Dose: 6mg SQ
Max Dose/24 Hrs: Two 6mg inj separated by at least 1 hr; consider a 2nd dose only if some response to 1st inj was observed

Migraine

W/ or w/o Aura:
May use lower doses (1-5mg) if side effects are dose limiting

Inj:
Max Single Dose: 6mg SQ
Max Dose/24 hrs: Two 6mg inj separated by at least 1 hr; consider a 2nd dose only if some response to 1st inj was observed

Spray:
5mg, 10mg, or 20mg
Additional Dose: May administer 1 additional dose at least 2 hrs after 1st dose if migraine has not resolved or returns after transient improvement
Max: 40mg/24 hrs
The 5mg and 20mg doses are given as a single spray in 1 nostril; 10mg dose may be achieved by administering a single 5mg dose in each nostril

Tab:
25mg, 50mg, or 100mg
Additional Dose: May administer a 2nd dose at least 2 hrs after 1st dose if migraine has not resolved or returns after transient improvement
Use After Inj: If migraine returns after initial treatment w/ inj, may give additional single tab (up to 100mg/day), w/ an interval of at least 2 hrs between tab doses
Max: 200mg/24 hrs

DOSING CONSIDERATIONS

Hepatic Impairment
Mild to Moderate:
Max Tab Single Dose: 50mg

Elderly
Start at lower end of dosing range

ADMINISTRATION

Oral/SQ/Nasal route

SQ
Use the 6mg single dose vial for patients receiving doses other than 4mg or 6mg; do not use autoinjector.
Avoid IM or intravascular delivery.

HOW SUPPLIED

Inj: 4mg, 6mg [prefilled syringe], 6mg/0.5mL [vial]; **Spray:** 5mg, 20mg [6^{S}]; **Tab:** 25mg, 50mg, 100mg

CONTRAINDICATIONS

Ischemic coronary artery disease (CAD) (eg, angina pectoris, history of MI, documented silent ischemia), coronary artery vasospasm (eg, Prinzmetal's angina), Wolff-Parkinson-White syndrome or arrhythmias associated w/ other cardiac accessory conduction pathway disorders, history of stroke or transient ischemic attack, history of hemiplegic/basilar migraine, peripheral vascular disease, ischemic bowel disease, uncontrolled HTN, and severe hepatic impairment. Recent use (w/in 24 hrs) of another 5-HT$_1$ agonist, or of an ergotamine-containing or ergot-type medication (eg, dihydroergotamine, methysergide). Concurrent administration or recent use (w/in 2 weeks) of an MAO-A inhibitor.

WARNINGS/PRECAUTIONS

Use only where a clear diagnosis of migraine headache or (Inj) cluster headache has been established. Reconsider diagnosis of migraine or (Inj) cluster headache before treating any subsequent attacks if patient does not respond to the 1st dose of therapy. Serious cardiac adverse reactions (eg, acute MI) reported. May cause coronary artery vasospasm. Perform cardiovascular (CV) evaluation in triptan-naive patients w/ multiple CV risk factors (eg, increased age, diabetes, HTN, smoking, obesity, strong family history of CAD) prior to therapy; if negative, consider administering 1st dose under medical supervision and perform an ECG immediately following administration. Consider periodic CV evaluation in intermittent long-term users w/ multiple CV risk factors. Sensations of tightness, pain, pressure, and heaviness in the precordium, throat, neck, and jaw, usually noncardiac in origin, reported; perform cardiac evaluation if at high cardiac risk. Life-threatening cardiac rhythm disturbances (eg, ventricular tachycardia, ventricular fibrillation leading to death) reported; d/c if these occur. Cerebral/subarachnoid hemorrhage and stroke reported; d/c therapy if a cerebrovascular event occurs. Patients w/ migraine may be at increased risk of certain cerebrovascular events. Exclude other potentially serious neurological conditions prior to therapy in patients not previously diagnosed w/ migraine or (Inj) cluster headache or in patients who present w/ atypical symptoms. May cause noncoronary vasospastic reactions (eg, peripheral vascular ischemia, GI vascular ischemia/infarction, splenic infarction, Raynaud's syndrome); rule out therapy-related vasospastic reactions before additional therapy is given. May cause transient/permanent blindness and significant partial vision loss. Overuse of acute migraine drugs may lead to exacerbation of headache; detoxification, including drug withdrawal, and treatment of withdrawal symptoms may be necessary. Serotonin syndrome may occur; d/c if suspected. Significant elevation in BP, including hypertensive crisis w/ acute impairment of organ systems, reported. Anaphylactic/anaphylactoid reactions may occur. Seizures reported; caution w/ history of epilepsy or conditions associated w/ a lowered seizure threshold. **Spray/Tab:** Safety of treating >4 headaches/30 days not known. **Spray:** Local irritative symptoms reported.

ADVERSE REACTIONS

Inj: Tingling, warm/hot/burning/pressure sensation, feeling of heaviness, tightness, numbness, flushing, chest/throat discomfort, inj-site reaction, weakness, neck pain/stiffness, dizziness/vertigo, drowsiness/sedation. **Spray:** Disorder/discomfort of nasal cavity/sinuses, N/V, bad/unusual taste. **Tab:** Paresthesia, warm/cold sensation, chest/neck/throat/jaw pain and other pressure sensations, malaise/fatigue.

DRUG INTERACTIONS

See Contraindications. Serotonin syndrome reported w/ SSRIs, SNRIs, TCAs, or MAOIs.

PREGNANCY AND LACTATION

Pregnancy: Category C.
Lactation: Excreted in human milk (Inj); avoid breastfeeding for 12 hrs after administration.

MECHANISM OF ACTION

Selective 5-HT$_{1B/1D}$ receptor agonist; thought to be due to the agonist effects at the 5-HT$_{1B/1D}$ receptors on intracranial blood vessels and sensory nerves of the trigeminal system, which result in cranial vessel constriction and inhibition of proinflammatory neuropeptide release.

PHARMACOKINETICS

Absorption: Spray: Bioavailability (approx 17%); C_{max}=5ng/mL (5mg), 16ng/mL (20mg). Tab: Bioavailability (approx 15%); C_{max}=18ng/mL (25mg), 51ng/mL (100mg). Inj: Bioavailability (97%); C_{max}=74ng/mL (manual inj, deltoid), 61ng/mL (manual inj, thigh), 52ng/mL (autoinjector, thigh); T_{max}=12 min (manual inj, deltoid). **Distribution:** V_d=2.7L/kg (spray/tab), 50L (Inj); plasma protein binding (approx 14-21%); found in breast milk (Inj). **Metabolism:** Via MAO-A; indole acetic acid (IAA) (major metabolite). **Elimination:** Spray: Urine (3% unchanged, 42% IAA); $T_{1/2}$=2 hrs. Tab: Urine (60%, mostly IAA or the IAA glucuronide), feces (40%); $T_{1/2}$=2.5 hrs. Inj: Urine (22% unchanged, 38% IAA); $T_{1/2}$=115 min.

ASSESSMENT

Confirm diagnosis of migraine or (Inj) cluster headache and exclude other potentially serious neurologic conditions and noncoronary vasospastic reactions prior to therapy. Assess for CV disease, HTN, hemiplegic/basilar migraine, hypersensitivity to drug, and any other conditions where treatment is cautioned or contraindicated. Assess hepatic function, pregnancy/nursing status, and for possible drug interactions. Perform CV evaluation in triptan-naive patients w/ multiple CV risk factors.

MONITORING

Monitor for signs/symptoms of cardiac events, cerebrovascular events, peripheral vascular ischemia, GI vascular ischemia/infarction, serotonin syndrome, hypersensitivity reactions, BP, and other adverse reactions. Perform periodic CV evaluation in intermittent long-term users w/ risk factors for CAD.

PATIENT COUNSELING

Inform that therapy may cause CV side effects and anaphylactic/anaphylactoid reactions. Instruct to seek

medical attention if such signs/symptoms occur. Inform that use of acute migraine drugs for ≥10 days/month may lead to an exacerbation of headache; encourage to record headache frequency and drug use (eg, by keeping a headache diary). Inform about the risk of serotonin syndrome. Inform that drug may cause somnolence and dizziness; instruct to evaluate ability to perform complex tasks after administration of drug. Inform that medication should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus; instruct to notify physician if breastfeeding or planning to breastfeed. **Inj:** Instruct to read instructions prior to use and advise on proper use, storage, and disposal of inj. Advise to avoid IM or intravascular delivery, and to use inj sites w/ adequate skin and SQ thickness to accommodate length of needle. **Spray:** Inform that local irritation of the nose and throat may occur and that symptoms will generally resolve in <2 hrs. Instruct on proper use of spray and caution to avoid spraying in eyes.

STORAGE

2-30°C (36-86°F). **Spray/Inj:** Protect from light.

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