

MyguardTM 2.5 Nasal Spray

Zolmitriptan

Presentation

MyguardTM 2.5 Nasal Spray: Each actuation delivers Zolmitriptan USP 2.5 mg.

Description

Zolmitriptan is an antimigraine agent. It binds with high affinity to 5-HT_{1B/1D} receptors. The therapeutic activity of Zolmitriptan for the treatment of migraine headache can most likely be attributed to the agonist effects at the 5-HT_{1B/1D} receptors on intracranial blood vessels and sensory nerves of the trigeminal system which results in cranial vessel constriction and inhibition of pro-inflammatory neuropeptide release.

Indications

Zolmitriptan Nasal Spray is indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older.

Dosage and administration

The recommended starting dose is 1 spray (2.5 mg) in one nostril. Maximum recommended single dose is 2 sprays (5 mg). If the migraine has not resolved by 2 hours after taking Zolmitriptan, or returns after a transient improvement, a second dose may be administered at least 2 hours after the first dose. The maximum daily dose is 4 sprays (10 mg) in any 24-hours period.

Side effects

Sore or irritated nose, sensitive skin, especially around the nose, dry mouth, unusual taste in the mouth, nausea, tiredness, dizziness, weakness, burning or tingling feeling, pain, tightness, pressure, or heaviness in the chest, throat, neck, or jaw, slow or difficult speech, faintness, breaking out in a cold sweat, problems with vision, weakness or numbness of an arm or leg, fast, pounding, or irregular heartbeat, bloody diarrhea, vomiting, sudden or severe stomach pain, sudden weight loss, paleness or blue color of the fingers and toes, shortness of breath, swelling of the eyes, face, lips, tongue, or throat, difficulty breathing or swallowing, rash, hoarseness, pain.

Contraindication

- Ischemic coronary artery disease, other significant underlying cardiovascular diseases, or coronary artery vasospasm including Prinzmetal's angina
- Wolff-Parkinson-White Syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders
- History of stroke, transient ischemic attack (TIA) or history of hemiplegic or basilar migraine because these patients are at higher risk of stroke
- Peripheral vascular disease (PVD)
- Ischemic bowel disease
- Uncontrolled hypertension
- Known hypersensitivity to Zolmitriptan

Warning & precautions

- Myocardial Ischemia, Myocardial Infarction and Prinzmetal's Angina: Perform cardiac evaluation in patients with multiple cardiovascular risk factors.
- Arrhythmias: Discontinue dosing if occurs.
- Chest/throat/neck/jaw pain, tightness, pressure, or heaviness: Generally not associated with myocardial ischemia; evaluate for coronary artery disease in patients at high risk.
- Cerebral hemorrhage, subarachnoid hemorrhage, and stroke: Discontinue dosing if occurs.
- Gastrointestinal ischemic events, peripheral vasospastic reactions: Discontinue dosing if occurs.
- Medication Overuse Headache: Detoxification may be necessary.
- Serotonin syndrome: Discontinue dosing if occurs.
- Increase in blood pressure: very rarely associated with significant events.

Use in pregnancy and lactation

Pregnancy Category C. There are no adequate and well controlled studies in pregnant women and lactating mother.

Use in Children: Safety and effectiveness in pediatric patients have not been established.

Use in Geriatric patients: Safety and effectiveness in aged 65 and over have not been established.

Drug interaction

Zolmitriptan nasal spray is contraindicated with Ergot-containing drugs, Monoamine Oxidase-A Inhibitors, Other 5-HT₁ Agonists, Selective Serotonin Reuptake Inhibitors/Serotonin Norepinephrine Reuptake Inhibitors.

Overdose

There is no experience with acute overdose.

Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial Pack

MyguardTM 2.5 Nasal Spray: Each bottle contains Zolmitriptan clear solution adequate for 20 metered doses.



Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
™ Trademark