

Sumatriptan BP 10 mg

Composition

Each spray delivers Sumatriptan BP 10 mg.

Suma Nasal Spray is an aqueous suspension of microfine Sumatriptan BP 10 mg for topical administration to the nasal mucosa by means of a metering, atomizing spray pump.

Pharmacology

Sumatriptan binds with high affinity to human cloned 5 HT_{1B/1D} receptors. Sumatriptan presumably exerts its therapeutic effects in the treatment of migraine headache through 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 pre-inflammatory neuropeptide release.

Indications

Suma is indicated for acute treatment of migraine with or without aura in adults.

Limitations of Use:

- Use only if a clear diagnosis of migraine headache has been established.
- Not indicated for the prophylactic therapy of migraine attacks.
- Not indicated for the treatment of cluster headache.

Dosage and administration**Route of administration:** Nasal

- Single dose of 10 mg of nasal spray
- Maximum dose in a 24 hour period: 30 mg; separate doses by at least one hour

Or as directed by the physician**Contraindications:**

- History of coronary artery disease or coronary vasospasm
- Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders
- History of stroke, transient ischemic attack, or hemiplegic or basilar migraine
- Peripheral vascular disease
- Ischemic bowel disease
- Uncontrolled hypertension
- Recent (within 24 hours) use of another 5 HT₁ agonist (e.g., another triptan) or of an ergotaminecontaining medication
- Concurrent or recent (past 2 weeks) use of monoamine oxidase A inhibitor
- Hypersensitivity to sumatriptan (angioedema and anaphylaxis seen)
- Severe hepatic impairment

Warning & Precautions

- **Myocardial ischemia/infarction and Prinzmetal's angina:** Perform cardiac evaluation in patients with multiple cardiovascular risk factors
- **Arrhythmias:** Discontinue Suma 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 Suma if occurs
- **Gastrointestinal ischemia and reactions, peripheral vasospastic reactions:** Discontinue Suma if occurs
- **Medication overuse headache:** Detoxification may be necessary
- **Serotonin syndrome:** Discontinue Suma if occurs
- **Increase in blood pressure:** Hypertensive crisis can occur
- **Hypersensitivity reactions:** Angioedema and anaphylaxis can occur
- **Seizures:** Use with caution in patients with epilepsy or a lowered seizure threshold
- **Local irritation:** Burning and abnormal taste can occur

Side effects

Common side effects: Unusual or unpleasant taste in the mouth; pain, burning, numbness, or tingling in the nose or throat; runny or stuffy nose after using the nasal medicine.

Rare side effects : Anxiety, burning sensation, discomfort of the nasal cavity and throat, general feeling of illness or tiredness & vision changes.

Use in pregnancy and lactation

There are no adequate and well-controlled studies in pregnant women and lactating mother.

Use in children and adolescents

Suma is not recommended for use in patients younger than 18 years of age

Drug Interactions

With Medicine : Sumatriptan nasal spray is contraindicated with Ergot-Containing Drugs, Monoamine Oxidase-A Inhibitors, Other 5-HT₁ Agonists and Selective Serotonin Reuptake Inhibitors/Serotonin Norepinephrine Reuptake Inhibitors.

With food and others: No interaction with foods.

Overdose

No specific data is available on the overdose of Sumatriptan 10mg nasal spray.

Storage

Store between 20°C - 25°C temperature.

Do not store in the refrigerator or freezer.

Do not test before use

Packing

Each bottle contains Sumatriptan aqueous suspension adequate for 120 metered sprays.

* Further information is available on request.



Manufactured by:

The ACME Laboratories Ltd.
Dhulivita, Dhamrai, Dhaka, Bangladesh

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