Abridged Prescribing Information:

Active Ingredient: RIZORA 5 / 10 mg tabs contain Rizatriptan Benzoate 5mg/10mg

Indication: Acute treatment of the headache phase of migraine attacks, with or without aura in adults. Rizatriptan should not be used prophylactically. **Dosage & Administration:** Adults 18 years of age and older: The recommended dose is 10 mg daily. Other medicinal products in a lower strength (5mg) are available and should be used by those patients requiring a lower dose. Redosing: doses should be separated by at least two hours; no more than two doses should be taken in any 24-hour period. For headache recurrence within 24 hours: if headache returns after relief of the initial attack, one further dose may be taken. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients used in the formulation. Concurrent administration of monoamine oxidase (MAO) inhibitors or use within two weeks of discontinuation of MAO inhibitor therapy. Patients with severe hepatic or severe renal insufficiency. Patients with a previous cerebrovascular accident (CVA) or transient ischemic attack (TIA). Moderately severe or severe hypertension or untreated mild hypertension. Established coronary artery disease, including ischemic heart disease (angina pectoris, history of myocardial infarction, or documented silent ischemia), signs and symptoms of ischemic heart disease, or Prinzmetal's angina. Peripheral vascular disease. Concomitant use of rizatriptan and ergotamine, ergot derivatives (including methylsergide), or other 5-HT1B/1D receptor agonists. **Warnings & Precautions:** Myocardial Ischemia, Myocardial Infarction, and Prinzmetal's Angina, Arrhythmias, Chest, Throat, Neck and/or Jaw Pain/Tightness/Pressure, Cerebral hemorrhage, subarachnoid hemorrhage, and stroke have occurred in patients treated with 5-HT1 agonists, and some have resulted in fatalities. Overuse of acute migraine drugs (e.g., triptans for 10 or more days per month) may lead to exacerbation of headache. Serotonin Syndrome, Increase in Blood Pressure. **Pregnancy & Lactation:** Rizatriptan should be used during pregnancy only if clearly needed. Caution should be exercised when administering rizatriptan to women who are breast-feeding. Infant exposure should be minimized by avoiding breast-feeding for 24 hours after treatment. **Drug Interaction:** The dose of RIZORA ODS should be adjusted in propranolol-treated patients, as propranolol has been shown to increase the plasma AUC of rizatriptan by 70%. Ergot-containing drugs have been reported to cause prolonged vasospastic reactions. Cases of serotonin syndrome have been reported during co-administration of triptans and selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs). RIZORA ODS is contraindicated in patients taking MAO-A inhibitors and non-selective MAO inhibitors. **Adverse Reactions:** The most common undesirable effects were dizziness, somnolence, and asthenia/fatigue. **Overdose:** Rizatriptan 40 mg (administered as either a single dose or as two doses with a two-hour interdose interval) was generally well tolerated in over 300 adult patients; dizziness and somnolence were the most common drug-related adverse effects. In addition, based on the pharmacology of rizatriptan, hypertension or other more serious cardiovascular symptoms could occur after overdose. Gastrointestinal decontamination, (e.g. gastric lavage followed by activated charcoal) should be considered in patients suspected of an overdose with Rizatriptan. Clinical and electrocardiographic monitoring should be continued for at least 12 hours, even if clinical symptoms are not observed. The effects of haemo- or peritoneal dialysis on serum concentrations of rizatriptan are unknown. *(For details, please refer full prescribing information)*

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