

COMPOSITION

Each film coated tablet contains Almotriptan Malate USP equivalent to Almotriptan 6.25 mg.

PHARMACOLOGY

Almotriptan is a selective and potent serotonin (5-HT_{1B/1D}) agonist. Almotriptan binds to specific serotonin receptors on meningeal arteries inhibiting the release of vasoactive peptides and causing constriction of the arteries. It has a limited effect on arteries supplying blood to the brain and little effect on cardiac and pulmonary vessels.

INDICATION

Almotriptan is prescribed to treat the acute headache phase of migraine attacks with or without aura. Almotriptan is the only oral triptan approved in the USA for the treatment of migraine in adolescent from 12 to 17 years of age.

DOSAGE AND ADMINISTRATION

Acute Treatment of Migraine Attacks:

The recommended dose of Altrip in adults and adolescents age 12 to 17 years is 6.25 mg to 12.5 mg, with the 12.5 mg dose tending to be a more effective dose in adults. If the headache is relieved after the initial Altrip (Almotriptan Malate) dose but returns, the dose may be repeated after 2 hours. The maximum daily dose should not exceed 25 mg. The safety of treating an average of more than four migraines in a 30-day period has not been established.

Hepatic Impairment:

The recommended starting dose of Almotriptan Malate in patients with hepatic impairment is 6.25 mg. The maximum daily dose should not exceed 12.5 mg over a 24-hour period.

Renal Impairment:

The recommended starting dose of Almotriptan Malate in patients with severe renal impairment is 6.25 mg. The maximum daily dose should not exceed 12.5 mg over a 24-hour period.

CONTRAINDICATION

As with other 5-HT_{1B/1D} receptor agonists, Almotriptan should not be used in patients with a history, symptoms or signs of ischaemic heart disease (myocardial infarction, angina pectoris, documented silent ischaemia, Prinzmetal's angina) or severe hypertension and uncontrolled mild or moderate hypertension. Concomitant administration with ergotamine, ergotamine derivatives (including methysergide) and other 5-HT_{1B/1D} agonists is contraindicated.

WARNING AND PRECAUTION

Hypersensitivity to the active substance or to any of the excipients. Patients with severe hepatic impairment, with a previous cerebrovascular accident (CVA) or transient ischaemic attack (TIA) peripheral vascular disease.

SIDE EFFECTS

Serious cardiac reactions, including myocardial infarction, have occurred following the use of Almotriptan Malate tablets. These reactions are extremely rare and most have been reported in patients with risk factors predictive of CAD (Coronary Artery Disease).

USE IN PREGNANCY AND LACTATION

Pregnancy Category C. There is no data regarding excretion of almotriptan in human milk.

USE IN CHILDREN AND ADOLESCENTS

Almotriptan is not indicated for use in patients under 12 years of age but in adolescent from 12 to 17 years of age indicated.

DRUG INTERACTION

These drugs have been reported to cause prolonged vasospastic reactions. Cases of life-threatening serotonin syndrome have been reported during combined use of triptans and selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs).

OVERDOSAGE

No case of overdose has been reported. The most frequently reported adverse event in patients receiving 150 mg (the highest dose administered to patients) was somnolence.

STORAGE

Store below 30°C temperature in a cool & dry place. Protect from light. Keep out of the reach of children.

HOW SUPPLIED

Each box contains 10 tablets in Alu-Alu blister pack.

Manufactured by:

NIPRO JMI Pharma Ltd.

Chauddagram, Cumilla, Bangladesh.