

RAGIL™

Rasagiline Mesylate INN Tablet

DESCRIPTION

RAGIL™ is a preparation of Rasagiline. Rasagiline is a selective, irreversible MAO-B inhibitor indicated for the treatment of idiopathic Parkinson's disease. The results of a clinical trial designed to examine the effects of Rasagiline on blood pressure when it is administered with increasing doses of tyramine indicates the functional selectivity can be incomplete when healthy subjects ingest large amounts of tyramine while receiving recommended doses of Rasagiline. The selectivity for inhibiting MAO-B diminishes in a dose-related manner.

INDICATIONS

RAGIL™ is indicated for the treatment of Parkinson's disease.

DOSAGE AND ADMINISTRATION

- Monotherapy: 1 mg once daily.
- As adjunct without levodopa: 1 mg once daily.
- As adjunct to levodopa: 0.5 mg once daily. Increase dose to 1 mg daily as needed for sufficient clinical response.
- Patients taking ciprofloxacin or other CYP1A2 inhibitors: 0.5 mg once daily.
- Patients with mild hepatic impairment: 0.5 mg once daily. Rasagiline should not be used in patients with moderate or severe hepatic impairment.

CONTRAINDICATIONS

Concomitant use of meperidine, tramadol, methadone, propoxyphene dextromethorphan, St. John's wort, cyclobenzaprine, or another (selective or non-selective) MAO inhibitor.

SIDE EFFECTS

- Flu syndrome, arthralgia, depression, dyspepsia
- Edema, fall, cough, and insomnia

PRECAUTION AND WARNING

May cause hypertension (including severe hypertensive syndromes) at recommended doses. May cause serotonin syndrome when used with antidepressants. May cause falling asleep during activities of daily living, daytime drowsiness, and somnolence. May cause hypotension, especially orthostatic. May cause or exacerbate dyskinesia. Decreasing the levodopa dose may lessen or eliminate this side effect. May cause hallucinations and psychotic-like behavior. May cause impulse control/compulsive behaviors. May cause withdrawal-emergent hyperpyrexia and confusion. Increased risk of melanoma: monitor patients for melanoma on a regular basis.

USE IN PREGNANCY AND LACTATION

Pregnancy Category C. There are no adequate and well-controlled studies of Rasagiline in pregnant women. Rasagiline should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Rasagiline is administered to a nursing woman.

PHARMACEUTICAL PRECAUTION

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

PACKAGING

RAGIL™ 0.5 Tablet: Box containing 3 strips of 10 tablets each. Each tablet contains Rasagiline Mesylate INN equivalent to Rasagiline 0.5 mg.

RAGIL™ 1 Tablet: Box containing 3 strips of 10 tablets each. Each tablet contains Rasagiline Mesylate INN equivalent to Rasagiline 1 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LIMITED

TONGI, GAZIPUR, BANGLADESH

TM TRADEMARK

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