



AricTM

Istradefylline

Presentation

AricTM 20: Each tablet contains Istradefylline INN 20 mg

Description

The precise mechanism by which Istradefylline exerts its therapeutic effect in Parkinson disease is unknown. In studies, Istradefylline is demonstrated to be an adenosine A_{2A} receptor antagonist.

Indications and Usage

Istradefylline is an adenosine receptor antagonist indicated as adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease experiencing "off" episodes.

Dosage and Administration

The recommended dosage of Istradefylline is 20 mg administered orally once daily. The dosage may be increased to a maximum of 40 mg once daily, based on individual need and tolerability. Patients who smoke 20 or more cigarettes per day (or the equivalent of another tobacco product) the recommended dosage is 40 mg once daily.

Patients with Hepatic Impairment

Maximum recommended dosage with moderate hepatic impairment is 20 mg once daily, use of Istradefylline in patients with severe hepatic impairment should be avoided.

Use in Pregnancy & Lactation

Pregnancy:

Use of Istradefylline during pregnancy is not recommended. Based on studies it may cause fetal harm.

Lactation:

There are no data on the presence of Istradefylline in human milk, the effects of Istradefylline on the breastfed infant, or on milk production. Caution should be exercised when administered to a nursing woman.

Use in Children

Safety and effectiveness of Istradefylline in pediatric patients have not been established.

Side Effects

The most common adverse reactions of Istradefylline are dyskinesia, dizziness, constipation, nausea, hallucination, and insomnia.

Precautions

Monitor patients for dyskinesia or exacerbation of existing dyskinesia. If hallucinations / psychotic behavior / impulse control / compulsive behaviors occurs then consider dosage reduction or stop Istradefylline.

Contraindications

Istradefylline is contraindicated in patients with known hypersensitivity to any component of this drug, and in patients with severe hepatic impairment.

Drug Interactions

The recommended maximum dosage of Istradefylline with concomitant use of strong CYP 3A4 inhibitors (Ketoconazole) is 20 mg once daily and avoid use with strong CYP 3A4 inducers (Rifampicin).

Overdose

There is limited clinical experience regarding human overdose with Istradefylline. If an overdose occurs, Istradefylline treatment should be discontinued and supportive treatment should be administered as clinically indicated.

Storage

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

Commercial Pack

AricTM 20: Each box contains 2 blister strips of 10 tablets.