FDA approved istradefylline as an add-on treatment to levodopa/carbidopa in adult patients with Parkinson’s disease (PD) experiencing "off" episodes. An off episode is a time when a patient’s medications are not working well, causing an increase in PD symptoms such as tremor and difficulty walking. The new agent is an adenosine receptor antagonist.

Istradefylline’s effectiveness in treating off episodes in patients with PD who are already being treated with levodopa/carbidopa was shown in four 12-week, placebo-controlled clinical studies with 1,143 participants. In all four studies, patients treated with istradefylline experienced a statistically significant decrease from baseline in daily "off" time compared with patients receiving a placebo.

The recommended dosage is 20 mg orally once daily, with or without food, and may be increased to a maximum of 40 mg once daily. For patients with moderate hepatic impairment, the maximum-recommended dosage is 20 mg once daily; use in patients with severe hepatic impairment should be avoided. For patients who smoke 20 or more cigarettes per day (or the equivalent of another tobacco product), the recommended dosage is 40 mg once daily.

The most common adverse reactions are involuntary muscle movement, dizziness, constipation, nausea, hallucination, and insomnia. Patients should be monitored for development of dyskinesia or exacerbation of existing dyskinesia. If hallucinations, psychotic behavior, or impulsive/compulsive behavior occurs, a dosage reduction or stoppage of istradefylline should be considered. Use during pregnancy is not recommended. Women of childbearing potential should be advised to use contraception during treatment.

Medication Monitor Categories:
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