

AZILECT[®] Fact Sheet

- Once-daily AZILECT[®] (rasagiline tablets) is indicated as initial monotherapy in early Parkinson's disease (PD) and as adjunct therapy to levodopa in moderate-to-advanced disease.
- AZILECT[®] is the first once-daily oral Parkinson's disease therapy approved by the Food and Drug Administration (FDA).
- For the treatment of early Parkinson's disease, the recommended dose of AZILECT[®] is 1 mg administered once-daily. As additional therapy for patients currently being treated with other Parkinson's medications, the initial recommended dose of AZILECT[®] is 0.5 mg administered once-daily. For patients who require additional clinical response, the dose may be increased to 1 mg administered once-daily.
- AZILECT[®] is a novel, potent, irreversible monoamine oxidase inhibitor.
- AZILECT[®] blocks the breakdown of dopamine, a chemical messenger in the brain that helps to control and coordinate movement.
- AZILECT[®] offers the following benefits:
 - Management of individual motor symptoms and improvement of overall motor function in early PD. Reducing "off" time (periods of poor overall functioning when the effects of levodopa wear off and symptoms return or are not adequately controlled) and controlling symptoms and improving overall motor function when used in conjunction with levodopa in moderate-to-advanced disease.
 - Convenient once-daily dosing, without titration; the first PD medication to be approved for once-daily dosing.
- The new drug application (NDA) for AZILECT[®] was submitted to the Food and Drug Administration (FDA) by Teva Neuroscience, Inc. on Sept. 5, 2003.
- FDA approval for AZILECT[®] was received May 17, 2006.

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- FDA approval of AZILECT[®] (rasagiline tablets) is based on demonstrated positive effects on Parkinson's symptoms in three Phase III clinical trials involving over 1,500 patients and additional safety data.
 - “(TVP-1012) in **Early Monotherapy for Parkinson's Disease Outpatients**” (TEMPO) — AZILECT[®] used as initial monotherapy in early PD.
 - “**Parkinson's Rasagiline: Efficacy and Safety in the Treatment of Off**” (PRESTO) — AZILECT[®] added to optimal, stable dosage of levodopa/carbidopa and to other concomitant PD therapies in moderate-to-advanced PD.
 - “**Lasting effect in Adjunct therapy with Rasagiline Given Once-daily**” (LARGO) — AZILECT[®] added to optimized dosage of levodopa and to other concomitant PD therapies in moderate-to-advanced PD. This study also included a COMT inhibitor as a comparator.
- The TEMPO and PRESTO trials were conducted in the United States and Canada by the Parkinson's Study Group (PSG). The PSG (www.Parkinson-Study-Group.org) is a non-profit, cooperative group of Parkinson's disease experts from medical centers in the United States and Canada who are dedicated to improving treatment for persons affected by Parkinson's disease.
- AZILECT[®] is in pharmacies nationwide.
- The development of AZILECT[®] is part of a long-term alliance for co-development in Parkinson's disease and European marketing between Teva Pharmaceutical Industries Ltd. and H. Lundbeck A/S.
- The brand name of rasagiline in the EU and Israel is also AZILECT[®]. The European Medicines Agency (EMA) granted marketing authorization for AZILECT[®] on Feb. 22, 2005. It also has been submitted for regulatory review in Canada (Sept. 23, 2003) and currently is still under review.
- AZILECT[®] was developed by Teva based on research originating from the Technion, Israel Institute of Technology.
- AZILECT[®] (rasagiline tablets) is indicated for the treatment of the signs and symptoms of Parkinson's disease (PD) both as initial therapy alone and to be added to levodopa later in the disease. The effectiveness of AZILECT was shown in patients with early PD who were receiving AZILECT as initial therapy alone and who were not receiving any other PD therapy. The effectiveness of AZILECT as adjunct therapy was shown in patients with PD who were treated with levodopa.
 - Patients should not take AZILECT if they are currently taking meperidine as it could possibly result in a serious reaction such as coma or death.
 - Patients should not take AZILECT with tramadol, methadone, propoxyphene, dextromethorphan, St. John's wort, mirtazapine, or cyclobenzaprine.
 - Patients should not take AZILECT with other monoamine oxidase inhibitors (MAOIs), amphetamines, cold remedies containing decongestants and weight-

reducing preparations containing pseudoephedrine, phenylephrine, phenylpropanolamine, or ephedrine in order to avoid a possibly dangerous increase in blood pressure. Symptoms of this reaction include severe headache, blurred vision, difficulty thinking, seizures, chest pain, unexplained nausea or vomiting, or signs or symptoms of a stroke. Patients or caregivers should seek immediate medical attention if these symptoms or other unusual symptoms occur.

- **In order to prevent a possibly dangerous increase in blood pressure, patients taking AZILECT should avoid foods and beverages high in tyramine content such as aged cheeses, air-dried meats, pickled herring, yeast extract, aged red wines, tap/draft beers, sauerkraut, and soy sauce.**
- Patients taking AZILECT should not have elective surgery requiring general anesthesia, and should not receive cocaine or other local anesthesia that contains ingredients that could raise blood pressure.
- Patients should inform their physician if they are taking, or planning to take, any prescription or over-the counter drugs, especially antidepressants and ciprofloxacin.
- Patients with moderate to severe liver disease or a tumor of the adrenal gland should not take AZILECT.
- All PD patients are advised to monitor for melanoma (skin cancer) frequently and see a dermatologist on a regular basis.

Side effects seen with AZILECT (rasagiline tablets) alone are headache, joint pain and indigestion; and when taken with levodopa are uncontrolled movements (dyskinesias), accidental injury, nausea, weight loss, constipation, low blood pressure when standing, joint pain, vomiting, dry mouth, rash, and sleepiness. Patients should tell their doctor about these and any other side effects they experience when taking AZILECT.

Please see accompanying additional important information.

To learn more about AZILECT[®], please call 1-877-4-AZILECT.

AZILECT[®] is a registered trademark of Teva Pharmaceutical Industries Ltd.

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