

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
January 08, 2010

**FORM 6-K**

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**Report of Foreign Private Issuer**

**Pursuant to Rule 13a-16 or 15d-16  
under the Securities Exchange Act of 1934**

For the month of December 2009

Commission File Number 0-16174

**Teva Pharmaceutical Industries Limited**

(Translation of registrant's name into English)

**5 Basel Street, P.O. Box 3190**

**Petach Tikva 49131 Israel**

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F   X  

Form 40-F           

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):           

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

[www.tevapharm.com](http://www.tevapharm.com)

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**For Immediate Release**

**FDA APPROVES Newly REVISED Prescribing Information FOR AZILECT<sup>®</sup>  
reducing Medication AND FOOD Restrictions**

**JERUSALEM (December 14, 2009)** - Teva Pharmaceutical Industries, Ltd. (NASDAQ:TEVA) today announced the U.S. Food and Drug Administration (FDA) approved the newly revised prescribing information for AZILECT<sup>®</sup> (rasagiline tablets) reducing medication and food restrictions. This update was based on clinical data that confirmed the mechanism of action of AZILECT<sup>®</sup> as a selective MAO-B (monoamine oxidase-B) inhibitor at the recommended doses of 1 mg and 0.5 mg.

The newly approved prescribing information reflects reduced concerns regarding the use of AZILECT<sup>®</sup> together with certain medications, including many over-the-counter cough/cold medications. In addition, patients taking AZILECT<sup>®</sup> no longer need to follow a general dietary restriction of ordinary levels of tyramine, an amino acid found in certain foods and beverages, such as air-dried and fermented meats, aged cheeses and most soybean products. However, due to potential mild increased sensitivity in some patients, ingestion of very high levels of tyramine (e.g., >150 mg) should be avoided by patients taking MAO inhibitors.

"The FDA's decision to modify the AZILECT<sup>®</sup> prescribing information emphasizes the benefit to patients of AZILECT<sup>®</sup> MAO-B selectivity at recommended doses," said Daniel Kremens, M.D., Assistant Professor of Neurology and Co-Director of the Parkinson's Disease and Movement Disorders Division at Jefferson Medical College of Thomas Jefferson University in Philadelphia. "This is good news for patients and physicians as it reconfirms the safety and convenience of AZILECT<sup>®</sup>."

"We are pleased with this important change in the prescribing information of AZILECT<sup>®</sup> as it removes a barrier for some physicians, and some patients, living with Parkinson's disease," said Jon Congleton, VP and General

Manager, U.S., Teva Neuroscience. "Physicians can now better focus on what is really most important, which is helping patients receive a proven efficacious and safe treatment, at diagnosis early in Parkinson`s disease, and throughout the course of the disease."

### ***About the Tyramine Study***

The tyramine study, submitted to the FDA as the basis for the change in the prescribing information, supported the selectivity of AZILECT<sup>®</sup> for inhibition of MAO-B at approved doses, 1 mg and 0.5 mg. Non selective MAO inhibitors may interfere with the breakdown and elimination of tyramine in the body, which can induce hypertensive reactions.

The tyramine study was a double-blind, placebo-controlled, randomized, dose-ranging study of rasagiline using a positive control (phenelzine), a known non-selective MAO inhibitor, and a comparator drug (selegiline). This study was part of a Phase IV commitment to the FDA at the time of AZILECT<sup>®</sup> approval. The study results were based on Tyramine Sensitivity Factor (TSF), which measures the ratio of tyramine pressor dose before (baseline) and after MAO inhibitor administration.

In the study, 179 healthy male and female volunteers, aged 40 to 70 years received escalating doses of oral tyramine from 25 mg up to 800 mg administered under fasting conditions. TSF was calculated as the tyramine dose associated with three consecutive increases from baseline in systolic blood pressure (SBP) 30 mm Hg over 10 minutes (tyramine pressor dose) in period one divided by the dose associated with the same change in SBP in period three.

Geometric mean TSFs of all doses of rasagiline were substantially lower than the TSF for phenelzine. TSFs of various doses of rasagiline were comparable to those of selegiline and placebo.

### ***About AZILECT<sup>®</sup>***

AZILECT<sup>®</sup> (rasagiline tablets) is indicated for the treatment of the signs and symptoms of Parkinson's disease (PD) as initial therapy alone and to be added to levodopa later in the disease.

AZILECT<sup>®</sup> is now available in 39 countries, including the U.S., Canada, Israel, Mexico and all of the European Union countries, where it is marketed by Teva in collaboration with Lundbeck A/S as part of a long-term strategic alliance.

### ***About Parkinson's disease***

Parkinson's disease is an age-related degenerative disorder of the brain. Symptoms can include: tremor, stiffness, slowness of movement, and impaired balance. An estimated five million people worldwide suffer from the disease, with an average age of onset of about 60 years.

### *About Teva*

Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA), headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the leading generic pharmaceutical company. The company develops, manufactures and markets generic and innovative pharmaceuticals and active pharmaceutical ingredients. Over 80 percent of Teva's sales are in North America and Western Europe.

### **Teva's Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995:**

This release contains forward-looking statements, which express the current beliefs and expectations of management. Such statements are based on management's current beliefs and expectations and involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic equivalents, the extent to which we may obtain U.S. market exclusivity for certain of our new generic products and regulatory changes that may prevent us from utilizing exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Neurontin<sup>®</sup>, Lotrel<sup>®</sup>, Protonix<sup>®</sup> and Eloxatin<sup>®</sup>, the current economic conditions, competition from brand-name companies that are under increased pressure to counter generic products, or competitors that seek to delay the introduction of generic products, the effects of competition on our innovative products, especially Copaxone<sup>®</sup> sales, dependence on the effectiveness of our patents and other protections for innovative products, the impact of consolidation of our distributors and customers, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, our ability to achieve expected results through our innovative R&D efforts, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the uncertainty surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, the regulatory environment and changes in the health policies and structures of various countries, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, our ability to successfully identify, consummate and integrate acquisitions, the potential exposure to product liability claims to the extent not covered by insurance, our exposure to fluctuations in currency, exchange and interest rates, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, our ability to enter into patent litigation settlements and the intensified scrutiny by the U.S. government, the termination or expiration of governmental programs and tax benefits, impairment of intangible assets and goodwill, environmental risks, and other factors that are discussed in this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").

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Teva Pharmaceutical Industries Ltd. Web Site: [www.tevapharm.com](http://www.tevapharm.com)

### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(Registrant)

By: /s/ Eyal Desheh

Name: Eyal Desheh  
Title: Chief Financial Officer

Date December 14, 2009

