

# BIOGEN IDEC

## IMPORTANT DRUG WARNING

MARCH 2005

Dear Healthcare Professional:

Biogen Idec wishes to inform you of an important update to the prescribing information for AVONEX<sup>®</sup> (Interferon beta-1a). Since AVONEX was introduced to the market in 1996, Biogen Idec has been committed to gathering further information on the safety and efficacy of AVONEX. In post-marketing experience severe hepatic injury, including cases of hepatic failure, has been reported rarely in patients taking AVONEX.

In some cases, these events have occurred in the presence of other drugs that have been associated with hepatic injury. The potential for hepatic injury should be considered when AVONEX is used in combination with other products associated with hepatic injury, or when new agents are added to the regimen of patients already on AVONEX.

In March 2005, the WARNINGS; PRECAUTIONS, Drug Interactions; ADVERSE REACTIONS; ADVERSE REACTIONS, Post-Marketing Experience sections of the Prescribing Information; and the Medication Guide were updated to include this important new safety information. A copy of the revised full Prescribing Information and Medication Guide is enclosed. A summary of the changes is presented below.

### WARNINGS

This section has been revised to include the following information:

#### Hepatic Injury

Severe hepatic injury, including cases of hepatic failure, has been reported rarely in patients taking AVONEX<sup>®</sup>. Asymptomatic elevation of hepatic transaminases has also been reported, and in some patients has recurred upon rechallenge with AVONEX<sup>®</sup>. In some cases, these events have occurred in the presence of other drugs that have been associated with hepatic injury. The potential risk of AVONEX<sup>®</sup> used in combination with known hepatotoxic drugs or other products (e.g. alcohol) should be considered prior to AVONEX<sup>®</sup> administration, or when adding new agents to the regimen of patients already on AVONEX<sup>®</sup>. Patients should be monitored for signs of hepatic injury (see Precautions: Laboratory Tests).

### *IMPORTANT DRUG WARNING*

PRECAUTIONS, Drug Interactions

The section has been revised to include the following information: the potential for hepatic injury should be considered when AVONEX~ is used in combination with other products associated with hepatic injury, or when new agents are added to the regimen of patients already on AVONEX® (see WARNINGS: Hepatic Injury).

ADVERSE REACTIONS This section has been revised to include the following statement:

Hepatic injury, including hepatic failure and elevated serum hepatic enzyme

levels, has been reported in post-marketing experience (see WARNINGS:

Hepatic Injury).

The ADVERSE REACTIONS, Post-Marketing Experience section has been revised to add hepatic failure.

Additionally, the PRECAUTIONS, Information to Patients and Pregnancy sections of the Prescribing Information, and the Medication Guide were revised to include information regarding the AVONEX Pregnancy Registry. A summary of the changes is presented below.

PRECAUTIONS, Information to Patients and Pregnancy :

These sections have been revised to include the following statement:

If a woman becomes pregnant while taking AVONEX, consider enrolling her in the AVONEX Pregnancy Registry by calling 1-800-456-2255.

This new labeling will be included in packaging for AVONEX® (Interferon beta1a) manufactured after April 18, 2005. All packaging will reflect the name change of Biogen Idec.

Healthcare professionals should report any serious adverse events in patients treated with

AVONEX to Biogen Idec at 1-800-456-2255. Alternatively, this information may be reported to

FDA's Med Watch reporting system by telephone (1-800-FDA-1088), facsimile (1-800-FDA-1078), the Med Watch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or mailed to MedWatch, HF-2, 5600

Fishers Lane, Rockville, MD 20852-9787. For additional information, please contact Biogen Idec at 1-800-456-2255.

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Enclosures:

AVONEX® (Interferon beta-1a) Full Prescribing Information and Medication Guide 161023-1