biogen idec

Important Drug Warning

October 2005

Dear Healthcare Professional:

Biogen Idec wishes to inform you of new safety information which is being added to the prescribing information for ZEVALIN® (ibritumomab tiuxetan). Severe cutaneous or mucocutaneous reactions, some with fatal outcome, have been reported in association with the ZEVALIN therapeutic regimen in the post-marketing experience. Similar events have been associated with RITUXAN® (rituximab), a component of the ZEVALIN therapeutic regimen. The potential risk of these reactions should be considered when using the ZEVALIN therapeutic regimen. Patients experiencing a severe cutaneous or mucocutaneous reaction should not receive any further components of the ZEVALIN therapeutic regimen and should seek prompt medical evaluation.

In September 2005, the **BOXED WARNINGS, WARNINGS, and ADVERSE REACTIONS** sections of the Prescribing Information were updated to include this important new safety information. A copy of the revised full Prescribing Information is enclosed and a summary of the changes is presented below.

BOXED WARNINGS
This section has been revised to include the following information:

> "**Severe Cutaneous and Mucocutaneous Reactions:** Severe cutaneous and mucocutaneous reactions, some with fatal outcome, have been reported in association with the ZEVALIN therapeutic regimen. Patients experiencing a severe cutaneous or mucocutaneous reaction should not receive any further component of the Zevalin therapeutic regimen and should seek prompt medical evaluation. (see **WARNINGS** and **ADVERSE REACTIONS**)."

WARNINGS
This section has been revised to include the following information:

> "**Severe Cutaneous and Mucocutaneous Reactions (See BOXED WARNINGS and ADVERSE REACTIONS):** There have been postmarketing reports of erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous dermatitis, and exfoliative dermatitis in patients who received the ZEVALIN therapeutic regimen. Some of these events were fatal. The onset of the reactions was variable; in some cases, acute, (days) and in others, delayed (3-4 months). Patients experiencing a severe cutaneous or mucocutaneous reaction should not receive any further components of the ZEVALIN therapeutic regimen and should seek prompt medical evaluation."

Biogen Idec 14 Cambridge Center Cambridge, MA 02142 Phone 617 679 2000 www.biogenidec.com

ADVERSE REACTIONS

This section has been revised to include the following information:

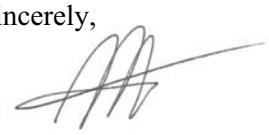
> "The most serious adverse reactions caused by the ZEVALIN therapeutic regimen include prolonged and severe cytopenias, infections (predominantly bacterial in origin), hemorrhage while thrombocytopenic (resulting in deaths), and allergic reactions (bronchospasm and angioedema). In addition, patients who have received the ZEVALIN therapeutic regimen have developed myeloid malignancies and dysplasias. Fatal infusion reactions have occurred following the infusion of Rituximab.
>
> In postmarketing reports, cutaneous and mucocutaneous reactions have been associated with the ZEVALIN therapeutic regimen. Please refer to the **BOXED WARNINGS** and **WARNINGS** sections for detailed descriptions of these reactions."

This new labeling will be included in ZEVALIN® (ibritumomab tiuxetan) kits manufactured after September 2005.

Healthcare professionals should report any serious adverse events in patients treated with ZEVALIN to Biogen Idec at 1-877-866-4332. Alternatively, this information may be reported to FDA's MedWatch reporting system by telephone (1-800-FDA-1088), facsimile (1-800-FDA-1078), the MedWatch website at www.fda.gov/medwatch, or mailed to MedWatch, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787.

For additional information, please contact Biogen Idec Medical Information at 1-877-878-4332.

Sincerely,



Mariska Kooijmans-Coutinho, MD, PhD
Senior Director, Drug Safety and Risk Management

Enclosures:
ZEVALIN® (ibritumomab tiuxetan) Full Prescribing Information
RITUXAN® (rituximab) Full Prescribing Information