



---

**Berlex, Inc.**

PO Box 1000  
Montville, NJ 07045  
Telephone: 973-487-2000

---

April 15, 2005

Dear Healthcare Professional:

At Berlex, Inc., we are committed to providing the multiple sclerosis (MS) community with information to help ensure the safety of patients. In view of the heightened attention to information about the safety profile of multiple sclerosis therapies, we wanted to remind you of the prescribing information for Betaseron® (interferon beta-1b) as it pertains to hepatic toxicity. Since market introduction in 1993, the Betaseron prescribing information has recommended liver function testing at regular intervals (one, three, and six months) following introduction to Betaseron therapy, and then periodically thereafter in the absence of clinical symptoms.

Hepatotoxicity has been a reported adverse reaction to all beta-interferons. There have been rare reports of serious hepatic injury including autoimmune hepatitis and severe liver damage leading to hepatic failure and transplant. These events were reported during post-marketing safety surveillance. In some cases, these hepatotoxic events reported for patients on beta-interferons have occurred in the presence of other drugs and/or co-morbid medical illnesses associated with hepatic injury.

During the 12 years since market introduction of Betaseron in the U.S., over 300,000 patient years of experience have been accumulated. Betaseron remains an efficacious and safe treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. In addition, the MS Pathways<sup>SM</sup> and B.E.T.A.<sup>SM</sup> \* Nurse programs continue to be dedicated to providing comprehensive patient support and education.

If we may be of further assistance, please feel free to contact Berlex Medical and Product Services at 1-888-BERLEX4, option 4 (1-888-237-5394, option 4) or visit our website at [www.berlex.com](http://www.berlex.com) and select "Products." A current package insert is enclosed.

Sincerely,

A handwritten signature in black ink, appearing to read "Adrian", enclosed within a hand-drawn oval.

Adrian L. Rabinowicz, MD  
Executive Director Medical Affairs-Therapeutics  
Berlex, Inc.

\*Betaseron, Education, Training & Assistance

BETASERON is approved for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations.

The most commonly reported adverse reactions are lymphopenia, injection-site reaction, asthenia, flu-like symptom complex, headache, and pain. BETASERON should be used with caution in patients with depression. Injection-site necrosis has been reported in 5% of patients in controlled trials. Patients should be advised of the importance of rotating injection sites. Female patients should be warned about the potential risk to pregnancy. Cases of anaphylaxis have been reported rarely. (See “Warnings,” “Precautions,” and “Adverse Reactions” sections of complete Prescribing Information.)

Please see accompanying complete Prescribing Information.