Dear Healthcare Professional:

At Bayer HealthCare Pharmaceuticals, we are committed to providing the multiple sclerosis (MS) community with information to help ensure the safety of patients. Bayer HealthCare Pharmaceuticals has established a prospective pregnancy registry to study the maternal and infant pregnancy outcome in women who have taken BETASERON® (Interferon beta-1b) at any point around the time of conception or during pregnancy. The FDA has mandated registries like these due to the limited information on this patient population acquired during premarketing clinical trials. Kendle International, a contract research organization, helps manage the Betaseron Pregnancy Registry on behalf of Bayer HealthCare Pharmaceuticals.

This Registry was established to evaluate the safety of BETASERON use during pregnancy. Information from the Registry may assist clinicians and patients in making an informed decision should exposure to BETASERON occur around the time of conception or during pregnancy.

In your practice, you may be aware of women of childbearing potential taking BETASERON who have become pregnant and who may be enrolled in this study.

If you or your patients would like to learn more about the registry please visit the BETASERON Pregnancy Registry website at www.betaseronpregnancyregistry.com or call MS Pathways (1-800-788-1467). Please refer to the package insert for full prescribing information on BETASERON. The Registry Coordinating Center can be contacted directly at:

Kendle International
Phone: 800-478-7049 (toll-free)
Fax: 800-800-1052 (toll-free)
Email: registry@kendle.com

We thank you in advance for your time and contribution.

Sincerely,

Fernando Dangond, MD
Director
Medical Affairs-Therapeutics
Bayer HealthCare Pharmaceuticals

Betaseron® (Interferon beta-1b) 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.

Bayer HealthCare Pharmaceuticals

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