HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use BETASERON safely and effectively. See full prescribing information for BETASERON.

BETASERON (interferon beta-1b) for injection, for subcutaneous use
Initial U.S. Approval: 1993

---------- RECENT MAJOR CHANGES ----------

Dosage and Administration (2.3)	9/2015
Warnings and Precautions, Thrombotic Microangiopathy (5.7)	12/2015
Warnings and Precautions, Drug-induced Lupus Erythematosus (5.10)	4/2016

---------- INDICATIONS AND USAGE ----------

BETASERON is an interferon beta indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis. (1)

---------- DOSAGE AND ADMINISTRATION ----------

- For subcutaneous use only (2.1)
- The recommended dose is 0.25 mg every other day. Generally, start at 0.0625 mg (0.25 mL) every other day, and increase over a six-week period to 0.25 mg (1 mL) every other day. (2.1)
- Reconstitute lyophilized powder with supplied diluent (2.2)

---------- DOSAGE FORMS AND STRENGTHS ----------

For injection: 0.3 mg of lyophilized powder in a single-use vial for reconstitution (3)

---------- CONTRAINDICATIONS ----------

History of hypersensitivity to natural or recombinant interferon beta, albumin or mannitol (4)

---------- WARNINGS AND PRECAUTIONS ----------

- *Hepatic Injury:* Monitor liver function tests and signs and symptoms of hepatic injury; consider discontinuing BETASERON if serious hepatic injury occurs. (5.1, 5.11)
- *Anaphylaxis and Other Allergic Reactions:* Discontinue if anaphylaxis occurs. (5.2)
- *Depression and Suicide:* Advise patients to immediately report any symptom of depression and/or suicidal ideation; consider discontinuation of BETASERON if depression occurs. (5.3)
- *Congestive Heart Failure (CHF):* Monitor patients with CHF for worsening of cardiac symptoms; consider discontinuation of BETASERON if worsening of CHF occurs. (5.4)
- *Injection Site Necrosis and Reactions:* Do not administer BETASERON into affected area until fully healed; if multiple lesions occur, discontinue BETASERON until healing of skin lesions. (5.5)
- *Leukopenia:* Monitor complete blood count. (5.6, 5.11)
- *Thrombotic Microangiopathy:* Cases of thrombotic microangiopathy have been reported. Discontinue BETASERON if clinical symptoms and laboratory findings consistent with TMA occur. (5.7)
- *Flu-like Symptom Complex:* Consider analgesics and/or antipyretics on injection days. (5.8)
- *Drug-induced Lupus Erythematosus:* Cases of drug-induced lupus erythematosus have been reported. Discontinue BETASERON if patients develop new characteristic signs and symptoms. (5.10)

---------- ADVERSE REACTIONS ----------

In controlled clinical trials, the most common adverse reactions (at least 5% more frequent on BETASERON than on placebo) were: injection site reaction, lymphopenia, flu-like symptoms, myalgia, leukopenia, neutropenia, increased liver enzymes, headache, hypertonia, pain, rash, insomnia, abdominal pain, and asthenia. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Bayer HealthCare Pharmaceuticals at 1-888-842-2937 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

---------- USE IN SPECIFIC POPULATIONS ----------

Pregnancy: Based on animal data, may cause fetal harm. (8.1)

See 17 for PATIENT COUNSELING INFORMATION and FDA-Approved Medication Guide

Revised: 4/2016

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the Full Prescribing Information are not listed.