
CLICK HERE FOR MORE INFO ABOUT PRESCRIBING REBIF®

## REBIF® SLOWED DISABILITY PROGRESSION VS PLACEBO IN PATIENTS WITH A RANGE OF DISABILITY[1,2]

In the PRISMS study, patients treated with Rebif® had a 32% reduction in mean number of relapses at 2 years vs placebo (*P*<0.0001).* Rebif® was proven to slow the rate of disability progression in the full study cohort as well as in patient with higher Expanded Disability Status Scale (EDSS) scores.

### TOTAL PATIENT COHORT (BASELINE EDSS 0 TO 5.0)

**≈2X**

***Longer to confirmed disability progression (CDP)†***

21.3 months for Rebif® 44 mcg sc tiw, 11.9 months for placebo, Rebif® n=184 (HR-0.62, 95% CI, 43-0.91) *P*=0.0136; Placebo n=187

### HIGHER EDSS COHORT (BASELINE EDSS >3.5 TO 5.0)

**≈3X**

***Longer to confirmed disability progression (CDP)†***

21.3 months for Rebif® 44 mcg sc tiw, 7.3 months for placebo, Rebif® n=31 (HR-0.42, 95% CI, 0.18-0.99) *P*<0.05; Placebo n=28

See page 2 for study design.

*Results of primary endpoint—mean relapse count per patient at 2 years—were 1.73 with Rebif® 44 mcg (n=184) vs 2.56 with placebo (n=187). See PRISMS study design on next page for more details.

†Progression of disability was defined as an increase of at least 1 point in the Expanded Disability Status Scale (EDSS), sustained for at least 3 months.

The rate of serious adverse events in patients with EDSS >3.5 to 5.0 (regardless of causality) was 20% vs 11.3% for the total patient cohort (EDSS 0 to 5.0).

## INDICATION

Rebif® (interferon beta-1a) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

## IMPORTANT SAFETY INFORMATION

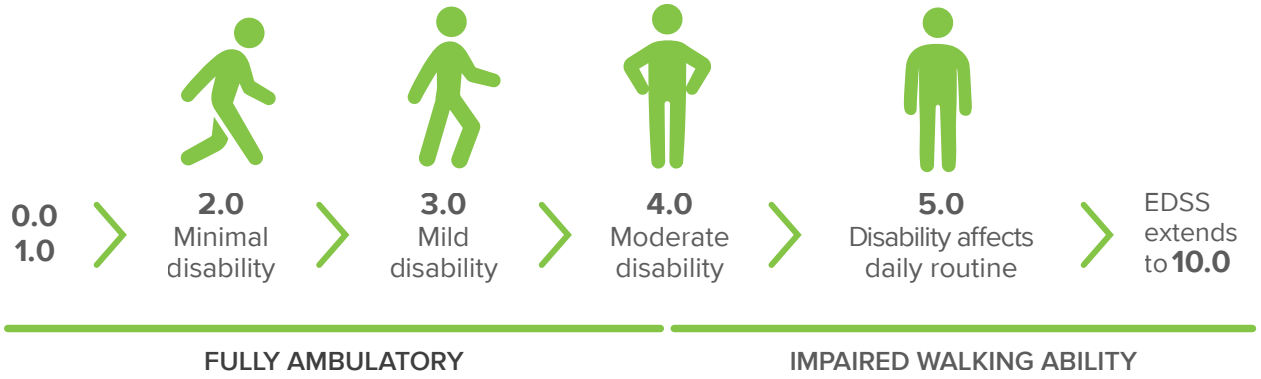
Rebif® is contraindicated in patients with a history of hypersensitivity to natural or recombinant interferon beta, human albumin, or any other component of the formulation.

Please see additional Important Safety Information on page 3 and the Full Prescribing Information and Medication Guide.

Rebif® (interferon beta-1a) subcutaneous injection

## ABOUT DISABILITY PROGRESSION[3,4]

Over time, the accumulation of relapses and incomplete healing can lead to a worsening of movement, walking ability, cognition, vision, and other symptoms MS can cause. This is called disability progression. Disability progression is measured using the Expanded Disability Status Scale, or EDSS.




**Consider Rebif® for patients who may need to change their treatment and have concerns about their mobility.**

## PRISMS STUDY DESIGN

**P**revention of **R**elapses and Disability by **I**nterferon β-1a **S**ubcutaneously in **M**ultiple **S**clerosis (**PRISMS**) was a double-blind, placebo-controlled study conducted over 2 years. Patients were randomly assigned Rebif® 44 mcg (n=184), Rebif® 22 mcg (n=189), or placebo (n=187), given 3 times weekly by subcutaneous injection. Outcomes measured included relapse rate, disability, MRI, safety, and antigenicity. Neurological assessments were conducted every 3 months.[1]

## IMPORTANT SAFETY INFORMATION (CONT'D)

Rebif® should be used with caution in patients with depression, a condition that is common in people with multiple sclerosis. Depression, suicidal ideation, and suicide attempts have been reported to occur with increased frequency in patients receiving interferon compounds, including Rebif®.

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Rebif® (interferon beta-1a) subcutaneous injection

# INDICATION AND IMPORTANT SAFETY INFORMATION

## INDICATION

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Severe liver injury, including some cases of hepatic failure requiring liver transplantation, has been reported rarely in patients taking Rebif®. The potential for liver injury should be considered when used in combination with other products associated with liver injury. Monitor liver function tests and patients for signs and symptoms of hepatic injury. Consider discontinuing Rebif® if hepatic injury occurs.

Anaphylaxis and other allergic reactions (some severe) have been reported as a rare complication of Rebif®. Discontinue Rebif® if anaphylaxis occurs.

In controlled clinical trials, injection site reactions occurred more frequently in Rebif®-treated patients than in placebo-treated and Avonex-treated patients. Injection site reactions including injection site pain, erythema, edema, cellulitis, abscess, and necrosis have been reported in the postmarketing setting. Do not administer Rebif® into affected area until fully healed; if multiple lesions occur, discontinue Rebif® until skin lesions are healed.

Decreased peripheral blood counts in all cell lines, including pancytopenia, have been reported in Rebif®-treated patients. In controlled clinical trials, leukopenia occurred at a higher frequency in Rebif®-treated patients than in placebo and Avonex-treated patients. Thrombocytopenia and anemia occurred more frequently in 44 mcg Rebif®-treated patients than in placebo-treated patients. Patients should be monitored for symptoms or signs of decreased blood counts. Monitoring of complete blood and differential white blood cell counts is also recommended.

Cases of thrombotic microangiopathy (TMA), some fatal, have been reported with interferon beta products, including Rebif®, up to several weeks or years after starting therapy. Discontinue Rebif® if clinical symptoms and laboratory findings consistent with TMA occur, and manage as clinically indicated.

Caution should be exercised when administering Rebif® to patients with pre-existing seizure disorders. Seizures have been temporally associated with the use of beta interferons, including Rebif®, in clinical trials and in postmarketing reports.

The most common side effects with Rebif® are injection-site disorders, headaches, influenza-like symptoms, abdominal pain, depression, elevated liver enzymes, and hematologic abnormalities.

Epidemiological data do not suggest a clear relationship between interferon beta use and major congenital malformations, but interferon beta may cause fetal harm based on animal studies. Data from a large human population-based cohort study, as well as other published studies over several decades, have not identified a drug-associated risk of major birth defects with interferon beta products during early pregnancy. Findings regarding a potential risk for low birth weight or miscarriage with the use of interferon beta products in pregnancy have been inconsistent.

# REFERENCES

**1.** PRISMS Study Group. Randomised double-blind placebo-controlled study of interferon β-1a in relapsing/remitting multiple sclerosis. *Lancet*. 1998;352(9139):1498-1504. **2.** Data on file. EMD Serono, Inc. PRISMS study report. **3.** Multiple Sclerosis Coalition. The use of disease-modifying therapies in multiple sclerosis. https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf. Updated September 2019. Accessed May 19, 2021. **4.** Kurtzke JF. Rating neurologic impairment in multiple sclerosis: an expanded disability status scale (EDSS). *Neurology*. 1983;33(11):1444-1452.



Please see Full Prescribing Information and Medication Guide.