

INDICATION AND IMPORTANT SAFETY INFORMATION

Indication

Rebif® (interferon beta-1a) is a prescription medicine used to treat relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Important Safety Information

Before beginning treatment, you should discuss the potential benefits and risks associated with Rebif with your healthcare provider.

Rebif can cause serious side effects. Tell your healthcare provider right away if you have any of the symptoms listed below while taking Rebif.

- **Behavioral health problems including depression and suicidal thoughts.** You may have mood problems including depression (feeling hopeless or feeling bad about yourself), and thoughts of hurting yourself or suicide
- **Liver problems or worsening of liver problems including liver failure.** **Symptoms may include** nausea, loss of appetite, tiredness, dark colored urine and pale stools, yellowing of your skin or the white part of your eye, bleeding more easily than normal, confusion, and sleepiness. During your treatment with Rebif you will need to see your healthcare provider regularly and have regular blood tests to check for side effects
- **Serious allergic and skin reactions. Symptoms may include** itching, swelling of your face, eyes, lips, tongue or throat, trouble breathing, anxiousness, feeling faint, skin rash, hives, sores in your mouth, or skin blisters and peels
- **Injection site problems. Symptoms at the injection site may include** redness, pain, swelling, color changes (blue or black), and drainage of fluid
- **Blood problems.** Rebif can affect your bone marrow and cause low red and white blood cell and platelet counts. In some people, these blood cell counts may fall to dangerously low levels. If your blood cell counts become very low, you can get infections and problems with bleeding and bruising. Your healthcare provider may ask you to have regular blood tests to check for blood problems
- **Seizures.** Some people have had seizures while taking Rebif

Rebif will not cure your MS but may decrease the number of flare-ups of the disease and slow the occurrence of some of the physical disability that is common in people with MS.

Do not take Rebif if you are allergic to interferon beta, human albumin, or any of the ingredients in Rebif.

Before you take Rebif, tell your healthcare provider if you have or have had any of the following conditions:

- mental illness, including depression and suicidal behavior
- liver problems, bleeding problems or blood clots, low blood cell counts, seizures (epilepsy), or thyroid problems
- you drink alcohol
- you are pregnant or plan to become pregnant. It is not known if Rebif will harm your unborn baby
- you are breastfeeding or plan to breastfeed. Rebif may pass into your breastmilk. Talk with your healthcare provider about the best way to feed your baby if you take Rebif

Tell your healthcare provider about all medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

The most common side effects of Rebif include:

- flu-like symptoms. You may have flu-like symptoms when you first start taking Rebif. You may be able to manage these flu-like symptoms by taking over-the-counter pain and fever reducers. For many people, these symptoms lessen or go away over time. Symptoms may include muscle aches, fever, tiredness, and chills
- stomach pain
- change in liver blood tests

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Rebif. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.