
FAMILY PLANNING
DOESN'T HAVE TO STOP WITH MS
Rebif®
(interferon beta-1a)
subcutaneous injection

## STARTING A FAMILY PLAN WITH MS

If you have MS and you're thinking about starting a family, it's important to plan ahead. Here are a few things to keep in mind during the family planning process:

Rebif® (interferon beta-1a) subcutaneous injection

Please see Rebif Prescribing Information and Medication Guide included in the pocket and Important Safety Information on pages 11-13.



# 1

**Choose an MS treatment** with family planning in mind. Talk to your healthcare provider about your options for treating your MS while you're planning to get pregnant, and ask if Rebif might be a good choice for you.

# 2

**Be prepared**. Make sure you ask the right questions and know the facts! Check out the back cover for questions to help you start the conversation with your healthcare provider.

# 3

**Get support** from friends, family, your partner, or your spouse. If you have any questions during the family planning process, ask your healthcare provider.

## 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.

# REBIF WAS PROVEN EFFECTIVE

When compared to a placebo, Rebif® (interferon beta-1a) was proven effective in treating relapsing multiple sclerosis (RMS) in 3 important ways: **fewer flare-ups, slowing the time to disability progression, and fewer new enlarging MRI brain lesions.**[*†]

The 2-year PRISMS study looked at 560 people with MS to see how they responded to treatment with Rebif. Pregnant women were not allowed to participate in the study, and women who became pregnant during the study were discontinued. One hundred eighty-nine people took Rebif 22 mcg; 184 took Rebif 44 mcg; and 187 took a placebo, all given under the skin 3 times a week.

The overall results for people taking Rebif 44 mcg showed:

**32%** **fewer**
relapses in 2 years
**1.73 relapses, on average, with Rebif**
**2.56 relapses, on average, with placebo**
**Rebif, n=184; placebo, n=187; *P*<0.0001**

**Nearly 2x** **longer to disability progression[‡]**
**21.3 months for Rebif**
**11.9 months for placebo**
**Rebif, n=184; placebo, n=187; *P*<0.05**

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**84%** **fewer**
**T1-weighted gadolinium-enhanced[§] (T1-Gd+) brain lesions[‡‖¶**] at 9 months**
**1.3 lesions with Rebif**
**8.0 lesions with placebo**
**Rebif, n=68; placebo, n=66; *P*<0.0001**

**78%** **fewer**
**new or enlarging T2 brain lesions[¶**] at 2 years**
**0.5 lesions with Rebif**
**2.25 lesions with placebo**
**Rebif, n=184; placebo, n=187; *P*<0.0001**

[*] Lesions detected with both T1-weighted gadolinium-enhanced (T1-Gd+) and PD/T2-weighted MRI.

[†] Refers to new lesions and total lesion burden or area as defined in the AAN and MS Council guidelines.

[‡] Disability progression was defined as an increase of at least 1 point in the Expanded Disability Status Scale that was sustained for at least 3 months.

[§] Gadolinium is a contrast medium injected prior to MRI scans. It passes through breaches in the blood-brain barrier and is therefore used to highlight new and active lesions. The usage of gadolinium greatly enhances the sensitivity of a T1-weighted MRI.

[‖] From a subgroup of 205 patients in the PRISMS study who received 11 consecutive monthly T2 and T1-Gd+ MRI scans beginning 1 month before treatment initiation.

[¶] Median number of lesions, per patient per scan, based on comparisons from rank-based ANOVA. Lesions detected with both T1-Gd+ and T2-weighted MRI. Median = a value in an ordered set that has an equal number of values higher and lower.

[**] The number of lesions represents new or enlarging lesions, per patient per scan.

## IMPORTANT SAFETY INFORMATION

Rebif can cause behavioral health problems including depression and suicidal thoughts. You may have mood problems including depression (feeling hopeless or feeling bad about yourself), thoughts of hurting yourself or suicide.

# REBIF SAFETY PROFILE

Rebif has a well-established safety profile and has been prescribed to over **145,000 patients in the US** since it was first approved by the FDA in 2002.

## SUPPORTING THE SAFETY PROFILE

**20+ years** of combined clinical trial data and real-world patient experience

*Common adverse events have been consistent across PRISMS and EVIDENCE clinical trials.

It's important to inform your healthcare provider of any side effects that you experience. There may be things you can do to help manage them.

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## COMMON SIDE EFFECTS SEEN IN THE PRISMS STUDY

This chart tells you the most common side effects and the percentage of people who experienced them during the study.

| Side effect | Placebo (%) | Rebif 44 mcg (%) |
|---|---|---|
| Headache | 63 | 70 |
| Influenza-like symptoms | 51 | 59 |
| Fatigue | 36 | 41 |
| Fever | 16 | 28 |
| Injection site reactions | 39 | 92 |

These are not all the possible side effects associated with Rebif.

## IMPORTANT SAFETY INFORMATION

Before you take Rebif, tell your healthcare provider if you have or have had mental illness, liver problems, bleeding problems or blood clots, low blood cell counts, seizures (epilepsy), thyroid problems, are pregnant or breastfeeding, or plan to become pregnant or breastfeed. Also tell your doctor whether you drink alcohol, and if you take other medicines, vitamins, or supplements.

# THE PREGNANCY REGISTRY

In a study conducted in Finland from 1996-2014 and Sweden from 2005-2014, data were collected about 2,831 pregnancy outcomes from women with MS.

In early pregnancy, some women were exposed to interferon beta while others were not exposed to any disease-modifying drugs.

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## *UNDERSTANDING THE REGISTRY DATA*

Of the 797 pregnancies that were only exposed to interferon beta, including Rebif® (interferon beta-1a), the data:

## *DID NOT IDENTIFY*

**a drug-associated risk of major birth defects** among the women exposed to interferon beta in early pregnancy.

## *DID NOT IDENTIFY*

**an increased risk of miscarriage or ectopic pregnancy.** However, limitations in obtaining complete data capture for these outcomes made the interpretation of these findings more difficult.

### IMPORTANT SAFETY INFORMATION

Before you take Rebif, tell your healthcare provider if:

- 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

# PLANNING STEP BY STEP

## PRE-PREGNANCY

When it comes to MS and family planning, it's important to take things one step at a time. That includes talking to your doctor about whether Rebif® (interferon beta-1a) may be right for you.

## PREGNANCY

Tell your healthcare provider right away if you become pregnant. Although the Pregnancy Registry data did not identify a drug-associated risk of major birth defects with interferon beta use during early pregnancy, it is not known if Rebif may harm your unborn baby.

## POST-PREGNANCY

Your healthcare provider can help you decide when it's the right time to start (or restart) Rebif after giving birth. Talk to them about the risk of relapses after birth and how soon you should consider starting treatment.

You should talk to your healthcare provider about the best way to feed your baby if you take Rebif, as it may pass into your breastmilk.



## 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

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## IMPORTANT SAFETY INFORMATION (CONTINUED)

- **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.

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**Knowing what to ask your healthcare provider about pregnancy when you have MS is important. Asking the right questions can help you stay informed throughout your family planning journey.**

**Start with these:**

- ☐ Can I take Rebif when trying to get pregnant?
- ☐ Are pregnancy symptoms different for women with MS?
- ☐ What can I expect to happen with relapses when I am pregnant?
- ☐ How can I protect myself against relapses after having my baby?
- ☐ What should I do about an MS treatment plan after my baby comes?
- ☐ What are my options for feeding my baby?
- ☐ Where can I get more information about pregnancy and MS?

To learn more about Rebif, visit
**Rebif.com**

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