Rebif®

Interferon beta - 1a (rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about REBIF.

It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you using REBIF against the benefits it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this information with your medicine.
You may want to read it again later.

What REBIF is for

REBIF belongs to a class of medicines known as interferons. The active substance of REBIF is interferon beta-1a, a recombinant human interferon beta produced in Chinese hamster ovary cells.

REBIF is used in patients who have relapsing forms of multiple sclerosis (MS). It is also approved for use in patients who have experienced a single clinical event likely to be a first sign of multiple sclerosis.

REBIF has been shown to reduce the number of attacks that occur, decrease the severity of attacks and increase the time between attacks. Treatment with REBIF also delays the progression in disability and lowers the number of times people need to be hospitalised because of attacks.

Your doctor may prescribe REBIF for another reason. Ask your doctor if you have any questions about why REBIF has been prescribed for you.

REBIF is not addictive.

The effects of the disease or of REBIF treatment may influence your ability to drive a car or operate machinery. You should discuss this with your doctor if you are concerned.

This medicine is available only with a doctor's prescription.

Before you use REBIF

When you must not use it

Do not use REBIF if you have an allergy to:

- interferon beta
- any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use REBIF if:

- you are feeling depressed (feeling of severe sadness and unworthiness) or have thoughts of suicide
- you have epilepsy that is not adequately controlled by treatment.

Tell your doctor if you are pregnant or intend to become pregnant.
Women of childbearing age should take appropriate contraceptive measures while using REBIF.

If you want to have children, you should discuss this matter with your doctor.

Do not use REBIF after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged, return it to your pharmacist for disposal.

There is limited experience with the use of REBIF in children.

If you are not sure whether you should start using REBIF, contact your doctor.

Before you start to use it

Tell your doctor before you start to use REBIF if you are breastfeeding or intend to breastfeed.
It is not known whether REBIF passes into breast milk. Your doctor will discuss with you the risks and benefits of using REBIF while you are breastfeeding.

Before starting REBIF, tell your doctor if you have or have had any of the following:

- seizures (fits or convulsions)
- depression
- heart disorders
- kidney disease
- liver disease
- problems with your thyroid
- blood disorder (e.g. low counts of platelets, red and white blood cells)

- allergy to any other medicines, foods, dyes or preservatives
- alcohol abuse.

REBIF has a potential for causing severe liver injury. Therefore, it is recommended that serum liver enzymes should be checked whilst taking REBIF.

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies that you buy without a prescription from your pharmacy, supermarket, naturopath or health food shop.

REBIF may interact with some other medicines that are broken down by the liver:

- medicine to treat epilepsy
- medicine used for sedation or to treat anxiety
- medicine to treat depression.

Your doctor may have to adjust the dose of your other medicines while you are using REBIF.

If you are not sure if you are taking any of these medicines, ask your doctor or pharmacist.
Your doctor and pharmacist have more information on medicines to be careful with or avoid while using REBIF.

The following medicines, which are commonly used by people with MS, may be taken while using REBIF:

- corticosteroids such as hydrocortisone, prednisone or prednisolone
- ACTH (adrenocorticotrophic hormone)
- flu vaccine.

How to use REBIF

Treatment with REBIF should be started under the supervision of a specialist doctor experienced in the treatment of MS.

Follow all directions given to you by your doctor, nurse or pharmacist carefully.
They may differ from the information contained in this leaflet.

How to inject

REBIF is intended for you to inject yourself by subcutaneous (under the skin) injection.

Your doctor or nurse will instruct and assist you in the procedure and technique of self-injection.

Do not attempt self-injection until you are sure of how to do it.

You may be prescribed:

- REBIF pre-filled syringe (REBIF PFS) for single injection. REBIF PFS can be used on its own or with a Rebiject II® injection device
- REBIF PFS in a RebiDose® single use autoinjector (RebiDose). REBIF PFS is pre-assembled in the RebiDose injection device and is also for single injection
- REBIF cartridge for multiple injections. The REBIF cartridge must be used with either the RebiSmart® or RebiSlide® re-usable autoinjection device.

Follow the Directions for Use supplied in the pack with the Rebiject II, RebiDose, RebiSmart or RebiSlide (See Product description).

Before the injection, you should allow the cold REBIF solution to reach room temperature. This will minimise discomfort during administration.

Do not inject REBIF if it contains particles or is not clear.

Where to inject

The best areas for injection are loose and soft (flabby) skin away from joints and nerves.

Use a different injection site each time you inject to lessen the risk of damage to the fat and tissues under the skin.

Suitable injection sites are:

- arms (upper back portion)
- stomach (except around navel and waistline)
- buttocks
- thighs (front and sides except at groin and knee).

Do not inject into any areas that have lumps, firm knots, depressions, pain or discolouration.

Talk to your doctor if you experience anything unusual when injecting.

How much to inject

Your doctor will tell you how much REBIF to inject.

When first starting treatment with REBIF, it is recommended to start at a lower dose and then increase the dose gradually over the first few weeks until you reach your maintenance dose.

The usual dose for patients with multiple sclerosis or those who have experienced a single clinical event is 44 micrograms injected subcutaneously three times a week.

One REBIF PFS or RebiDose can only be used for a single injection and must be discarded after use.

At the usual maintenance dose, one cartridge of REBIF is enough for three injections. This is usually for one week of treatment. If you are on a lower dose, e.g. at the start of treatment, one cartridge can last for more than one week.

Discard the cartridge within 21 days after first use even if it is not empty.

If you are not sure what to do, ask your doctor, nurse or pharmacist.

If you forget to inject it

If you forget an injection by one day, administer it the day after the missed dose and push back the days of injection for the remainder of the week by one

day. Resume your regular schedule the following week.

If you miss an injection by two days, skip the missed injection (do not double dose on any day) and resume regular schedule.

Ask your doctor if you are not sure what to do or have trouble remembering to inject your medicine.

If you inject too much

Immediately contact your doctor or the Poisons Information Centre (in Australia telephone 13 11 26) if you are concerned that you have given yourself too much REBIF.

While you are using REBIF

Things you must do

Tell your doctor immediately if you become pregnant while using REBIF.

Change the injection site each time you inject.
Today's injection should not be given in the same area as the last one. Keep a record of where and when you last gave yourself an injection. You may use a site again after waiting one week, if the skin area is not red or irritated. If all areas become tender, talk to your doctor about choosing other injection sites.

Before starting any new medicine, tell your doctor and pharmacist that you are using REBIF.

Tell any doctors, dentists, and pharmacists who treat you that you are using REBIF.

If you become pregnant while using REBIF, tell your doctor immediately.

Things you must not do

Do not use REBIF to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop using REBIF without first checking with your doctor.

Do not change the dose unless your doctor tells you to.

Things to be careful of

Tell your doctor if you become depressed or have suicidal thoughts while using REBIF.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are using REBIF.

REBIF helps most people with MS, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor if you notice any of the following and they worry you:

- injection site reactions including redness, swelling, bruising, pain
- flu-like symptoms including fever, chills, and muscular pain. Flu-like symptoms can be reduced by taking a fever reducing painkiller, such as paracetamol, before you inject and for 24 hours after you inject REBIF.
- headache or fatigue
- itching or rash
- abdominal pain
- diarrhoea or nausea
- muscle pain or aches, back pain or painful joints
- muscle stiffness or spasms, weakness, difficulty walking
- increased sweating.

Tell your doctor immediately if you experience any of the following:

- infected area at site of injection (swollen and painful area, with or without discharge)
- depression, problems with sleeping or suicidal thoughts
- anxiety/nervousness
- fits/convulsions
- extreme feeling of tiredness, particularly if this occurs with other symptoms, such as fever, sore throat and/or mouth ulcers
- problems with your eyes or vision
- spontaneous bruising or bleeding from gums or spontaneous blisters on skin
- fatigue, dizziness, shortness of breath, bruises, gum/nose bleeds, minor cuts bleed a lot, confusion, sleepiness, seizures, decreased urine, swollen legs or fever
  Some or all of these symptoms together may indicate a rare but serious disease of the blood.
- persistent rapid heartbeat or palpitations, insomnia, weight loss or weight gain, hair loss, tremor, neck lumps, irritability, abnormal menstrual cycles
  These symptoms alone or in combination may mean that your thyroid gland is not working properly and needs to be checked by your doctor.
- severe swelling (oedema), particularly around your eyes and in your ankles and feet or weight gain due to fluid retention
- foamy urine, which may be caused by excess protein in your urine
- loss of appetite accompanied by other symptoms such as nausea, vomiting, jaundice (yellow appearance to your skin colour). Such symptoms can be associated with a liver disorder and, rarely, liver failure.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you have:

- shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.
  These may be signs of an allergic reaction.

Some side effects may only be found when your doctor does laboratory tests to check your progress, e.g. decreased number of red blood cells, white blood cells or platelets, or the reduction in number of all blood cells, or disturbed liver function tests. These changes are usually reversible and mild, and most often do not require particular treatment.

There have been cases of lupus reported after treatment with medicines like REBIF. This occurs when the body's immune system doesn't recognise some part of the body as its own and attacks its own cells. This is uncommon to very rare.

Tell your doctor if you notice anything else that is making you feel unwell.
Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.
You may not experience any of them.

After using REBIF

Storage

Keep REBIF in a refrigerator where the temperature is between 2°C to 8°C (Refrigerate. Do not freeze) and it is not exposed to light.

Should refrigeration be temporarily unavailable, REBIF can be stored at or below 25°C for up to 14 days, then put back in the refrigerator and used before the expiry date.

Do NOT store it in the freezer.

REBIF cartridge must be used with a RebiSmart or RebiSlide reusable autoinjection device. The device containing a cartridge of REBIF must be stored in the device storage box.

Use REBIF PFS and RebiDose once only.
After injecting, you should discard the syringe or RebiDose even if you have not injected all of the contents.

Discard the REBIF cartridge within 21 days after first use, even if you have not injected all of the contents.

Cartridge should be used for multiple injections by one person only.

Keep this medicine where young children cannot reach it.

Disposal

Discard all sharps into a disposal unit.
Sharps are objects or devices having sharp points or edges capable of cutting or piercing the skin.

Ask your doctor or pharmacist what to do with any REBIF that has expired or is left over from your treatment.

Product description

What it looks like

REBIF is an injection solution available in REBIF PFS, RebiDose or REBIF cartridge.

REBIF PFS and RebiDose contain 0.5 mL of solution and must only be used for a single injection. They are available in packs of 12.

REBIF cartridge contains 1.5 mL of solution and is used for multiple injections. REBIF cartridges are available in packs of 4.

RebiSmart and RebiSlide autoinjection devices and needles for REBIF are provided separately by Merck Serono via your neurologist, MS nurse or MS Australia. Only validated needle sizes as specified in the Instructions for Use supplied with the RebiSmart and RebiSlide devices should be used.

Ingredients

Active Ingredient:

- interferon beta-1a (rch).

Inactive Ingredients:

- mannitol
- poloxamer
- methionine
- sodium hydroxide
- acetic acid
- water for injections
- benzyl alcohol.

REBIF does NOT contain lactose.

Sponsor

REBIF is supplied in Australia by:

Merck Serono Australia Pty Ltd
3-4/25 Frenchs Forest Road East
Frenchs Forest NSW 2086

For enquiries please call Merck Serono Australia Medical **Information on 1800 633 463**.

Australian Registration Numbers

REBIF 44 PFS
44 micrograms per 0.5 mL:
AUST R 133813

REBIF 44 PFS in RebiDose single use autoinjector
44 micrograms per 0.5 mL:
AUST R 174479

REBIF 44 cartridge
132 micrograms per 1.5 mL
(88 microgram per mL):
AUST R 165746

This leaflet was revised on 25 February 2016.

A015-0216

® Registered trademark