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Rebif (*interferon beta-1a*)

An overview of Rebif and why it is authorised in the EU

What is Rebif and what is it used for?

Rebif is a medicine used to treat patients with relapsing multiple sclerosis (MS). MS is a disease in which inflammation damages the protective insulation around nerves (demyelination) as well as the nerves themselves. Relapsing MS is the type of MS where the patient has attacks (relapses) between periods with no symptoms. Rebif's effectiveness has not been shown in patients with secondary progressive MS (the type of MS that comes after relapsing MS) that is not relapsing.

Rebif can also be used in patients who have had a single attack of demyelination accompanied by inflammation. It is used when the patient is considered to be at high risk of developing MS. Before using Rebif, doctors need to exclude other causes for the symptoms.

Rebif contains the active substance interferon beta-1a.

How is Rebif used?

Rebif can only be obtained with a prescription and treatment should be started by a doctor who has experience in the management of MS.

Rebif is available as a solution for injection in prefilled syringes, prefilled pens and cartridges for use in an electronic injection device.

The recommended dose of Rebif is 44 micrograms given three times a week by injection under the skin. A 22-microgram dose is recommended for patients who cannot tolerate the higher dose.

When first starting treatment with Rebif, the dose should be slowly increased from a starting dose of 8.8 micrograms three times a week to avoid side effects.

The patients can inject Rebif themselves once they have been trained. The doctor may advise the patient to take a fever-reducing painkiller before each injection and for 24 hours after injection to reduce the influenza (flu)-like symptoms that may occur as a side effect of treatment. All patients should be assessed at least once every two years.

For more information about using Rebif, see the package leaflet or contact your doctor or pharmacist.

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How does Rebif work?

The active substance in Rebif is the protein interferon beta-1a, one of a group of interferons that can be naturally produced by the body to help it fight against viruses and other attacks. In MS, the immune system (the body's natural defences) malfunctions and attacks parts of the central nervous system (the brain, spinal cord and optic nerve [nerve that sends signals from the eye to the brain]), causing inflammation that damages the nerves and the insulation around them. The exact way that Rebif works in MS is not yet known but the active substance, interferon beta-1a, seems to calm down the immune system, and prevents relapses of MS.

What benefits of Rebif have been shown in studies?

Rebif has been studied in 560 patients with relapsing MS. The patients had experienced at least two relapses in the previous two years. Patients received either Rebif (22 or 44 micrograms) or placebo (a dummy treatment) for two years. The study was then extended to four years. Rebif was more effective than placebo in reducing the number of relapses in relapsing MS. Relapses were reduced by about 30% over two years for both Rebif 22 and 44 micrograms compared with placebo, and by 22% (Rebif 22 micrograms) and 29% (Rebif 44 micrograms) over four years.

Rebif has also been studied in patients with secondary progressive MS. Rebif had no significant effect on the progression of disability, but the relapse rate was reduced by about 30%. Some effect on progression of disability could be seen, but only in the patients who had relapses in the two years before the start of the study.

Rebif (44 micrograms given once or three times a week) has also been compared with placebo in 515 patients who had experienced a single attack of demyelination. The probability of developing MS over 24 months was 62.5% for patients given Rebif three times a week and 75.5% for patients given Rebif once a week compared with 85.8% for patients given placebo.

What are the risks associated with Rebif?

The most common side effects with Rebif (which may affect more than 1 in 10 people) are flu-like symptoms, neutropenia, lymphopenia and leucopenia (low white blood cell counts), thrombocytopenia (low blood platelet counts), anaemia (low red blood cell counts), headache, inflammation and other reactions at the injection site, and increases in transaminases (liver enzymes).

Rebif must not be used in patients who have severe depression or have thoughts of suicide.

For the full list of side effects and restrictions with Rebif, see the package leaflet.

Why is Rebif authorised in the EU?

The European Medicines Agency decided that Rebif's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Rebif?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Rebif have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Rebif are continuously monitored. Side effects reported with Rebif are carefully evaluated and any necessary action taken to protect patients.

Other information about Rebif

Rebif received a marketing authorisation valid throughout the EU on 4 May 1998.

Further information on Rebif can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/rebif.

This overview was last updated in 11-2019.