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Betaferon (*interferon beta-1b*)

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

What is Betaferon and what is it used for?

Betaferon is a medicine used to treat adults who have multiple sclerosis (MS). MS is a disease in which inflammation damages the protective insulation around nerves (demyelination) as well as the nerves themselves. Betaferon is used in patients:

- who have experienced the signs of MS for the first time, and these are severe enough to need treatment with injected corticosteroids (anti-inflammatory medicines). Betaferon is used when the patient is considered to be at high risk of developing MS. Before using Betaferon, doctors need to exclude other causes for the symptoms;
- who have MS of the type known as 'relapsing-remitting', when the patient has attacks (relapses) between periods with no symptoms (remissions), in patients with at least two relapses within the last two years;
- who have secondary progressive MS (the type of MS that comes after relapsing-remitting MS), when their disease is active.

Betaferon contains the active substance interferon beta-1b.

How is Betaferon used?

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

Betaferon is available as a powder and solvent that are made up into a solution that supplies a dose of 250 micrograms. It is given by injection under the skin.

Treatment should start with 62.5 micrograms (a quarter of the dose) every other day, increasing progressively over 19 days to reach the recommended dose of 250 micrograms given every other day. Patients can inject Betaferon themselves once they have been trained. Betaferon treatment should be stopped in patients whose condition does not improve.

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

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How does Betaferon work?

The active substance in Betaferon is the protein interferon beta-1b, 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 Betaferon works in MS is not yet known but the active substance, interferon beta-1b, seems to calm down the immune system, and prevents relapses of MS.

What benefits of Betaferon have been shown in studies?

Betaferon was studied over a two-year period in 338 patients with relapsing remitting MS who were able to walk unaided, where it was compared with placebo (a dummy treatment). Betaferon was more effective than placebo in reducing the number of annual relapses: patients receiving the medicine had on average 0.84 relapses a year, when patients on placebo had 1.27.

Betaferon has also been studied in 1,657 patients in two studies of secondary progressive MS patients who were able to walk, where it was compared with placebo. One of the two studies showed a significant delay in the time to disability progression (31% risk reduction due to Betaferon) and in the time to becoming wheelchair bound (39%). In the other study, no delay in the time to disability progression was seen. In both studies, Betaferon showed a reduction (30%) in the number of clinical relapses.

Betaferon was also studied in 487 patients with a single demyelinating event, who received either Betaferon or placebo for two years. Betaferon was shown to reduce the risk of developing clinically defined MS: 28% of the patients who received Betaferon developed MS, compared with 45% of those who received placebo.

What are the risks associated with Betaferon?

The most frequent side effects with Betaferon are flu-like symptoms (including fever, chills, joint pain, malaise [feeling unwell], sweating, headache and muscle pain) and reactions at the site of injection. Side effects are common at the beginning of treatment but usually decrease with further treatment.

Betaferon must not be used in patients who have severe depression or have thoughts of suicide. Betaferon must not be used in patients who have decompensated liver disease (when the liver is damaged and can no longer work adequately).

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

Why is Betaferon authorised in the EU?

The European Medicines Agency decided that Betaferon'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 Betaferon?

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

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

Other information about Betaferon

Betaferon received a marketing authorisation valid throughout the EU on 30 November 1995.

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

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