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EPAR summary for the public

Betaferon

interferon beta-1b

This is a summary of the European public assessment report (EPAR) for Betaferon. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Betaferon.

What is Betaferon?

Betaferon is a powder and solvent, which is made into a solution for injection. It contains 250 micrograms (8 million international units - MIU) per ml of the active substance interferon beta 1b.

What is Betaferon used for?

Betaferon is used to treat adult patients who have multiple sclerosis (MS). MS is a disease of the nerves, in which inflammation destroys the protective sheath around the nerves. This is called 'demyelination'. Betaferon is used in patients:

- who have experienced the signs of MS for the first time, and these are severe enough to justify 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) within periods with no symptoms (remissions), in patients with at least 2 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.

The medicine can only be obtained with a prescription.



How is Betaferon used?

Betaferon treatment should be started by a doctor who has experience in the treatment of MS. The 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 (8 MIU) given every other day. Betaferon is given by injection under the skin. The patients can inject Betaferon themselves, provided that they have been trained. Betaferon treatment should be stopped in patients who fail to respond.

How does Betaferon work?

The active substance in Betaferon, interferon beta-1b, belongs to a group of medicines known as interferons. Interferons are natural substances produced by the body to help it fight against attacks such as infections caused by viruses. The exact way that Betaferon works in MS is not yet known but beta-interferon seems to reduce the activity of the immune system (the body's natural defences) and prevents the relapses of MS.

Interferon beta-1b is produced by a method known as 'recombinant DNA technology'. The interferon beta-1b is made by a bacterium that has received a gene (DNA), which makes it able to produce it. The replacement interferon beta-1b acts in the same way as naturally produced interferon beta.

How has Betaferon been studied?

Betaferon was studied over a two year period in 338 patients with relapsing remitting MS who were able to walk unaided, where its effectiveness was compared with placebo (a dummy treatment). The main measure of effectiveness was the reduction in the number of relapses.

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 a placebo. The main measure of effectiveness was the delay to progression of disability.

Betaferon was also studied in 487 patients with a single demyelinating event, who received either Betaferon or placebo for two years. The study measured the time it took for a patient to develop clinically defined MS.

What benefit has Betaferon shown during the studies?

In patients with relapsing remitting MS, 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.

One of the two studies in patients with secondary progressive MS 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 second trial, no delay in the time to disability progression was seen. In both trials, Betaferon showed a reduction in the number (30%) of clinical relapses.

In the study of patients with a single demyelinating event, 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 is the risk associated with Betaferon?

Very common side effects with Betaferon (seen in more than 1 patient in 10) are flu-like symptoms, fever, chills and injection site reactions (inflammation and pain at the site of injection). For the full list of all side effects reported with Betaferon, see the package leaflet.

Betaferon must not be used in people who have a history of hypersensitivity (allergy) to natural or recombinant interferon beta, human albumin or any of the other ingredients. Betaferon treatment must not be started during pregnancy. If a woman becomes pregnant while taking the medicine, she should consult her doctor. Betaferon must not be used in patients who are currently suffering from severe depression and/or have thoughts of suicide. Betaferon must not be used in patients who have decompensated liver disease (when the liver does not function normally).

Why has Betaferon been approved?

The CHMP decided that Betaferon's benefits are greater than its risks and recommended that Betaferon be granted marketing authorisation.

Betaferon was originally authorised under "Exceptional Circumstances", because, for scientific reasons, limited information was available at the time of approval. As the company had supplied the additional information requested, the "Exceptional Circumstances" ended on 3 April 2001.

Other information about Betaferon

The European Commission granted a marketing authorisation valid throughout the European Union for Betaferon on 30 November 1995.

The full EPAR for Betaferon can be found on the Agency's website: ema.europa.eu/Find/medicine/Human_medicines/European_Public_Assessment_Reports. For more information about treatment with Betaferon, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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