



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/354496/2011
EMA/H/C/000102

EPAR summary for the public

Avonex

interferon beta-1a

This document is a summary of the European public assessment report (EPAR) for Avonex. 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 Avonex.

What is Avonex?

Avonex is a powder and solvent in a vial, which are made up into a solution for injection, and a solution for injection in a pre-filled syringe or pre-filled pen. Each vial, syringe and pen contains 30 micrograms (6 million international units or 'MIU') of the active substance, interferon beta-1a.

What is Avonex used for?

Avonex is used to treat the following groups:

- patients with relapsing multiple sclerosis (MS). MS is a disease of the nerves, in which inflammation destroys the protective sheath around the nerves. This is called 'demyelination'. In relapsing MS the patient has attacks (relapses) within periods with no symptoms. Avonex slows the progression of disability and reduces the number of relapses;
- patients who have had a single attack of demyelination, when this is severe enough to justify treatment with injectable corticosteroids (anti-inflammatory medicines). It is used when the patient is considered to be at high risk of developing MS. Before using Avonex, doctors need to exclude other causes for the symptoms.

The medicine can only be obtained with a prescription.



How is Avonex used?

Avonex treatment should be started by a doctor who has experience in the management of MS.

In adults (aged 18 years or over), the recommended dose of Avonex is 30 micrograms, given by injection into a muscle once a week. To help patients adjust to treatment, the doctor may recommend that patients start with about half this dose once a week before increasing to the full dose. This can only be done with the pre-filled syringe, when it is fitted with a special device that attaches onto the syringe and only allows about half the dose of Avonex to be injected. The best dose to use in patients below 18 years of age is not known.

The site of injection should be varied each week. The patients can inject Avonex themselves if they have been trained appropriately. A painkiller that prevents fever can be given before each injection and for 24 hours after injection to reduce the influenza (flu)-like symptoms that may occur during the first few months of treatment. Avonex treatment should be stopped in patients who develop progressive (worsening) MS.

How does Avonex work?

The active substance in Avonex, interferon beta-1a, belongs to the group '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 Avonex works in MS is not yet known but interferon beta seems to calm the immune system down, and prevents relapses of MS.

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

How has Avonex been studied?

Avonex has been compared with placebo (a dummy treatment) in two main studies. The first study involved 301 patients aged 16 years and older with relapsing MS who had experienced at least two relapses in the previous three years or at least one relapse per year if they had had the disease for less than three years. Treatment continued for up to two years. The main measure of effectiveness was the number of patients whose disability got worse. The second study involved 383 adults who had experienced a single attack of demyelination and compared the ability of Avonex and placebo to reduce the risk of a second attack.

The company has not carried out any formal studies of patients under 16 years of age. However, it presented information from published studies on the use of Avonex in patients aged between 12 and 18 years.

What benefit has Avonex shown during the studies?

In the first study, 22% of the patients with relapsing MS who were treated with Avonex and 35% of the patients treated with placebo had a worsening of disability by the end of two years. In the second study, the estimated risk of having a second attack of demyelination was lower in the patients taking Avonex than in the patients taking placebo: with Avonex, the risk was 21% in two years and 35% in three years, whereas the risk with placebo was 39% in two years and 50% in three years.

In patients aged between 12 and 18 years, the published studies showed that the patients had a decrease in the rate of relapse. This may be due to Avonex treatment.

What is the risk associated with Avonex?

The most common side effects with Avonex (seen in more than 1 patient in 10) are headache, flu-like symptoms, pyrexia (fever), chills and sweating. These side effects decrease with continued treatment. The side effects are similar in adults and in children. For the full list of all side effects reported with Avonex, see the package leaflet.

Avonex must not be used in people who have had hypersensitivity (allergy) to natural or recombinant interferon beta, human albumin or any of the other ingredients. The pre-filled syringes and pens do not contain human albumin. Avonex must not be started during pregnancy. If a woman becomes pregnant while taking the medicine, she should consult her doctor. Avonex must also not be used in patients who are currently suffering from severe depression or have thoughts about committing suicide.

Why has Avonex been approved?

The CHMP decided that Avonex's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Avonex:

The European Commission granted a marketing authorisation valid throughout the European Union for Avonex on 13 March 1997. The marketing authorisation holder is Biogen Idec Limited. The marketing authorisation is valid for an unlimited period.

The full EPAR for Avonex 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 Avonex, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2011.