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Avonex (*interferon beta-1a*)

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

What is Avonex and what is it used for?

Avonex 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. In relapsing MS, the patient has attacks (relapses) between 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 need 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.

Avonex contains the active substance interferon beta-1a.

How is Avonex used?

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

Avonex is available as a solution for injection in a pre-filled syringe or pre-filled pen. Each syringe and pen contains 30 micrograms of interferon beta-1a.

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 a lower 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 the lower dose of Avonex to be injected.

The site of injection should be changed each week. Patients can inject Avonex themselves once they have been trained. A painkiller that prevents fever can be given before each injection and for 24 hours after injection to reduce the 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.

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

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How does Avonex work?

The active substance in Avonex 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 Avonex 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 Avonex have been shown in studies?

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. After two years, 22% of the patients who were treated with Avonex and 35% of the patients treated with placebo had a worsening of disability.

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 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.

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, which showed that they had a decrease in the rate of relapse, possibly due to Avonex treatment.

What are the risks associated with Avonex?

The most common side effects with Avonex (which may affect more than 1 in 10 people) 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.

Avonex 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 Avonex, see the package leaflet.

Why is Avonex authorised in the EU?

The European Medicines Agency decided that Avonex'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 Avonex?

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

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

Other information about Avonex

Avonex received a marketing authorisation valid throughout the EU on 13 March 1997.

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

This overview was last updated in 11-2019.