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Plegridy (*peginterferon beta-1a*)

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

What is Plegridy and what is it used for?

Plegridy is a medicine used to treat multiple sclerosis (MS), a disease in which inflammation damages the protective insulation around nerves (demyelination) as well as the nerves themselves. It is used specifically in adults with a type of MS known as relapsing-remitting MS, where the patient has flare-ups of symptoms (relapses) between periods of recovery (remissions).

Plegridy contains the active substance peginterferon beta-1a.

How is Plegridy used?

Plegridy can only be obtained with a prescription and treatment should be started under the supervision of a doctor experienced in treating MS.

Plegridy is available as an injection in pre-filled pens or pre-filled syringes, given every 2 weeks. The dose should be increased in two-week steps until the full dose is reached after 4 weeks.

Plegridy is given by injection under the skin of the abdomen, the arm or the thigh, or by injection into the thigh muscle using a different type of syringe. Patients can inject Plegridy themselves, provided that they have been trained.

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

How does Plegridy work?

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 Plegridy works in MS is not yet known but it seems to calm down the immune system, and prevents relapses of MS.

The active substance in Plegridy 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 Plegridy,

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this interferon has been 'pegylated' (attached to a chemical called polyethylene glycol). This decreases the rate at which the medicine is removed from the body and allows it to be given less often.

What benefits of Plegridy have been shown in studies?

Plegridy has been shown to reduce the rate of relapses in patients with relapsing-remitting MS in a main study which lasted two years and involved 1,516 patients. During the first year, patients were given Plegridy every two or four weeks, or placebo (a dummy treatment); during the second year, all patients were given Plegridy every two or four weeks. The main measure of effectiveness was the number of relapses that patients experienced over one year but the study also looked at other measures including how fast the patients' disability progressed.

During the first year, patients treated with Plegridy every two or four weeks experienced fewer relapses on average than patients on placebo: 0.26 and 0.29 relapses versus 0.40, respectively. The progression of disability was reduced in patients given Plegridy every two weeks but less clearly so in those given the medicine every four weeks. Plegridy continued to produce benefit in the second year of treatment.

This study was extended for two further years to investigate the long-term safety and efficacy of Plegridy, and available data from the extension phase at the time of approval were consistent with the results of the main study.

What are the risks associated with Plegridy?

The most common side effects with Plegridy (which may affect more than 1 in 10 people) are headache, muscle pain, joint pain, flu-like symptoms, pyrexia (fever), chills, asthenia (weakness), and erythema (reddening of the skin), pain or pruritus (itching) at the injection site.

Plegridy 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 Plegridy, see the package leaflet.

Why is Plegridy authorised in the EU?

The European Medicines Agency decided that Plegridy's benefits are greater than its risks and it can be authorised for use in the EU. The Agency considered that Plegridy given every two weeks has been shown to produce about a 30% reduction in the number of relapses in patients with relapsing-remitting MS compared with placebo, which is comparable to the effect of other MS medicines containing non-pegylated interferon beta, and is considered clinically relevant.

Also, the Agency considered Plegridy to be of greater benefit to patients when given every two weeks as compared to less frequent injections tested in the study. When Plegridy was given every four weeks its beneficial effect was smaller, and it was not possible to identify a group of patients in whom this less frequent dosing was considered appropriate.

With regards to the safety profile, the most common side effects observed during treatment with Plegridy are considered to be manageable and generally consistent with those seen with non-pegylated interferon medicines.

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

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

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

Other information about Plegridy

Plegridy received a marketing authorisation valid throughout the EU on 18 July 2014.

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

This overview was last updated in 11-2020.