EMA/325652/2014
EMEA/H/C/002827

EPAR summary for the public

Plegridy

peginterferon beta-1a

This is a summary of the European public assessment report (EPAR) for Plegridy. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Plegridy.

For practical information about using Plegridy, patients should read the package leaflet or contact their doctor or pharmacist.

What is Plegridy and what is it used for?

Plegridy is a medicine that contains the active substance peginterferon beta-1a. It is used to treat multiple sclerosis (MS), a disease in which inflammation destroys the protective sheath around the nerves. 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) followed by periods of recovery (remissions).

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 a solution for injection in pre-filled pens or pre-filled syringes that contain 63, 94 or 125 micrograms peginterferon beta-1a. Treatment should start with a dose of 63 micrograms, followed by a dose of 94 micrograms after two weeks, and then 125 micrograms every two weeks thereafter.

Plegridy is given by injection under the skin of the abdomen, the arm or the thigh. Patients can inject Plegridy themselves, provided that they have been trained. For further details see the package leaflet.

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How does Plegridy work?

In MS, the body's immune system malfunctions and attacks parts of the central nervous system (the brain and spinal cord), causing the inflammation that damages the nerve sheaths. The exact way that Plegridy works in MS is not yet known but the active substance in the medicine, peginterferon beta 1-a, seems to calm down the immune system (the body's natural defences) and prevents the relapses of MS.

Interferon beta 1-a is a form of a protein that is naturally produced by the body. The interferon in Plegridy is produced by a method known as 'recombinant DNA technology'. This means that it is made by cells that have received a gene (DNA), which makes them able to produce the human interferon. This interferon is then 'pegylated' (attached to a chemical called polyethylene glycol). This decreases the rate at which the substance is removed from the body and allows the medicine 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 1 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 medicines 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, myalgia (muscle pain), arthralgia (joint pain), influenza (flu)-like symptoms, pyrexia (fever), chills, asthenia (weakness), and erythema (reddening of the skin), pain or pruritus (itching) at the injection site.

Treatment with Plegridy must not be started during pregnancy. Plegridy must not be used in patients who are currently suffering from severe depression or have thoughts of suicide.

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

Why is Plegridy approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Plegridy's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP 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 CHMP 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 adverse events observed during treatment with Plegridy are considered to be manageable and generally consistent with those seen with non-pegylated interferon products.

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

A risk management plan has been developed to ensure that Plegridy is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Plegridy, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Plegridy

The European Commission granted a marketing authorisation valid throughout the European Union for Plegridy on 18 July 2014.

The full EPAR and risk management plan summary for Plegridy 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 Plegridy, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2014.