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EPAR summary for the public

PegIntron

peginterferon alfa-2b

This document is a summary of the European Public Assessment Report (EPAR) for PegIntron. 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 PegIntron.

What is PegIntron?

PegIntron is a medicine that contains the active substance peginterferon alfa-2b. It is available as a powder and solvent that are made up into a solution for injection, and as a single-use prefilled pen. These contain 50, 80, 100, 120 or 150 micrograms of peginterferon alfa-2b in 0.5 ml.

What is PegIntron used for?

PegIntron is used to treat long-term hepatitis C (a disease of the liver due to infection with the hepatitis C virus) in patients aged three years and older.

In adults (aged 18 years and older), PegIntron can be used in patients who have not been treated before or whose previous treatment failed. PegIntron can be given in a triple therapy combination with ribavirin and boceprevir to adults with type 1 hepatitis C whose liver is damaged but still able to work normally (compensated liver disease). In other adults with hepatitis C virus in their blood, including patients also infected with human immunodeficiency virus (HIV), PegIntron is given either with ribavirin (dual therapy) or on its own if they cannot take ribavirin.

Dual therapy with ribavirin is also used in previously untreated children and adolescents (aged between three and 17 years) as long as their liver is still working normally.

The medicine can only be obtained with a prescription.

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How is PegIntron used?

Treatment with PegIntron should be started and supervised by a doctor who has experience in the management of patients with hepatitis C. PegIntron is given once a week as an injection under the skin. In adults, it is used in combination treatments at a dose of 1.5 micrograms per kilogram body weight, or on its own at 0.5 or 1.0 micrograms/kg. In children and adolescents, the dose is 60 micrograms per square metre body surface area (calculated using the patient's height and weight). The duration of treatment depends on the patient's condition and response to treatment, and ranges from six months to a year. The doses of ribavirin and PegIntron may need to be adjusted for patients who experience side effects. Depending on the severity of the side effects treatment may have to be stopped altogether (including boceprevir).Patients can inject themselves once they have been trained appropriately. For more information, see the package leaflet.

How does PegIntron work?

The active substance in PegIntron, peginterferon alfa-2b, 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 they work in viral diseases is not fully understood, but it is thought that they act as immunomodulators (substances that modify how the immune system works). They may also block the multiplication of viruses.

Peginterferon alfa-2b is similar to interferon alfa-2b, which has been available in the European Union (EU) for a number of years. In PegIntron, the interferon alfa-2b has been '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. The interferon alfa-2b in PegIntron is produced by a method known as 'recombinant DNA technology': it is made by a bacterium that has received a gene (DNA), which makes it able to produce interferon alfa-2b. The replacement acts in the same way as naturally produced interferon alpha.

How has PegIntron been studied?

PegIntron, with or without ribavirin, has been compared with interferon alfa-2b in five main studies involving a total of over 6,000 adults with hepatitis C who had not been treated before, including 328 patients with cirrhosis and 507 patients also infected with HIV. The combination of PegIntron and ribavirin has also been studied in one study involving 1,354 adults whose previous treatment had failed and in one study involving 107 children and adolescents aged between three and 17 years who had not been treated before. The main measure of effectiveness was the level of hepatitis C virus circulating in the blood before and after six months or a year of treatment, and at 'follow-up', six months later. Some studies also looked at signs of improvement of the condition of the liver.

Two main studies involving 1,503 adult patients with type 1 hepatitis C and compensated liver disease investigated the effect of PegIntron in a triple therapy combination with ribavirin and boceprevir compared with PegIntron and ribavirin alone. The first study involved previously untreated patients while the second study involved patients who had failed previous treatment. The main measure of effectiveness in these studies was the number of patients who had no detectable hepatitis C virus in their blood 24 weeks after the end of the treatment and could therefore be considered to be cured.

What benefit has PegIntron shown during the studies?

In adults, PegIntron was more effective than interferon alfa-2b in patients who had not been treated before, with around a quarter of the patients responding to PegIntron alone and around a half responding to the combination of PegIntron and ribavirin. The combination of PegIntron with ribavirin

was effective in patients with cirrhosis and in patients infected with HIV. Around a quarter of the adults whose previous treatment had failed and around two-thirds of the children and adolescents responded to treatment with PegIntron and ribavirin.

In the studies on triple therapy in patients with type 1 hepatitis C and compensated liver disease, PegIntron in combination with ribavirin and boceprevir was shown to be more effective than the dual combination of PegIntron with ribavirin alone. Triple therapy led to an increase of about 30% in the number of previously untreated early responders who were cured. A 40% increase was seen among patients who had been treated before.

What is the risk associated with PegIntron?

In adults, the most common side effects with PegIntron (seen in more than 1 patient in 10) are viral infection, pharyngitis (sore throat), anaemia (low red blood cell counts), neutropenia (low levels of neutrophils, a type of white blood cell), loss of appetite, depression, anxiety, emotional lability (mood swings), impaired concentration, insomnia (difficulty sleeping), headache, dizziness, dyspnoea (difficulty breathing), cough, vomiting, nausea (feeling sick), abdominal pain (stomach ache), diarrhoea, dry mouth, alopecia (hair loss), pruritus (itching), dry skin, rash, myalgia (muscle pain), arthralgia (joint pain), musculoskeletal pain (pain in the muscles and bones), reactions at the site of the injection, inflammation at the site of the injection, fatigue (tiredness), asthenia (weakness), irritability, chills, pyrexia (fever), influenza (flu)-like illness and weight loss. In children and adolescents receiving PegIntron in combination with ribavirin, side effects were similar to adults, although reduced growth was also seen in more than 1 patient in 10. For the full list of all side effects reported with PegIntron, see the package leaflet.

PegIntron must not be used in people who are hypersensitive (allergic) to any interferon or any of the other ingredients. PegIntron must not be used in patients with a severe medical condition, severe liver problems, thyroid disease that is not controlled, epilepsy or other central nervous system problems. It must not be used in patients who have had severe heart disease or an auto-immune disease (a disease caused by the body's own defence system attacking normal tissue), or in children or adolescents who have had severe mental disorders, particularly severe depression, thoughts about committing suicide or suicide attempts. For a full list of restrictions, see the package leaflet.

Because PegIntron is linked to side effects such as depression, patients must be closely monitored during treatment. PegIntron is also linked to weight loss and reduced growth in children and adolescents. Doctors should take this risk into account when deciding whether to treat a patient before adulthood.

Why has PegIntron been approved?

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

The committee noted that the dual combination with ribavirin was shown to be effective against long-term hepatitis C virus infection in adults and children. There is also a marked increase in cure rates in patients with long-term type 1 hepatitis C when given the triple therapy of PegIntron in combination with ribavirin and boceprevir.

Other information about PegIntron:

The European Commission granted a marketing authorisation valid throughout the EU for PegIntron on 25 May 2000.

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

This summary was last updated in 03-2012.