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EPAR summary for the public

Pegasys

peginterferon alfa-2a

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

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

What is Pegasys and what is it used for?

Pegasys is an antiviral medicine used to treat:

- chronic (long-term) hepatitis B in adults and children from 3 years of age
- chronic hepatitis C in adults and children from 5 years of age.

Hepatitis B and C are diseases of the liver due to infection with the hepatitis B and C viruses, respectively. Pegasys is usually used alone for hepatitis B infection but is taken in combination with other medicines for hepatitis C. For more information about when to use this medicine in adults and children, see the summary of product characteristics (SmPC).

Pegasys contains the active substance peginterferon alfa-2a.

How is Pegasys used?

Pegasys is given by injection under the skin in the abdomen (belly) or thigh – once a week for 48 weeks for hepatitis B and once a week for between 16 and 72 weeks for hepatitis C.

The adult dose is usually 180 micrograms but the children's dose varies depending on their height and weight. Doses may need to be adjusted for patients who experience side effects.

Pegasys can only be obtained with a prescription and treatment should be started by a doctor who has experience in the treatment of hepatitis B or C. For further information see the package leaflet.

How does Pegasys work?

The active substance in Pegasys, peginterferon alfa-2a, belongs to the group 'interferons'. Interferons are natural substances produced by the body that help it fight infections caused by viruses. The exact way alfa interferons work in viral diseases is not fully understood, but it is thought that they act as immunomodulators (substances that modify how the immune system, the body's defence system, works). Alfa interferons may also block the multiplication of viruses.

Peginterferon alfa-2a is similar to interferon alfa-2a, which is widely available in the European Union (EU) as Roferon-A. In Pegasys, the interferon alfa-2a has been 'pegylated' (attached to a chemical called polyethylene glycol). This decreases the rate at which interferon is removed from the body and allows the medicine to be given less often.

What benefits of Pegasys have been shown in studies?

Studies show that Pegasys is effective at clearing signs of viral infection in adults and children with chronic hepatitis B or C.

Hepatitis B

Pegasys was more effective than lamivudine (another antiviral medicine) at clearing the hepatitis B virus in 2 studies of 1,372 adult patients. In these studies, the proportions of patients with no signs of viral activity in their blood 6 months after treatment were 32% with Pegasys and 22% with lamivudine among HBeAg-positive patients (those with the common type of the hepatitis B virus). Among 'HBeAg-negative' patients (those infected with a virus that has mutated and can be more difficult to treat), the clearance rate was 43% with Pegasys and 29% with lamivudine.

In a study of 151 children with hepatitis B aged 3 and above, 26% of those treated with Pegasys no longer had viral activity in their blood after 24 weeks, compared with 3% of those not given any treatment.

Hepatitis C

For hepatitis C, Pegasys has been studied on its own and in combination with other medicines.

Three studies of 1,441 adult patients showed that more patients taking Pegasys alone had no signs of hepatitis viral activity in their blood after treatment (28 to 39%) than patients taking interferon alfa-2a (8 to 19%).

Another study in 1,149 adult patients showed that the combination of Pegasys with ribavirin was also more effective than Pegasys alone (45% responders at follow-up compared with 24%) and as effective as the combination of interferon alfa-2a and ribavirin (39% responders).

Additional studies showed that peginterferon alfa-2a in combination with telaprevir and ribavirin or with boceprevir and ribavirin significantly increased the proportion of patients who responded to treatment compared with peginterferon alfa-2a plus ribavirin.

Finally, a study in 55 children showed similar effectiveness with the combination of Pegasys and ribavirin to that seen in adults treated with Pegasys and ribavirin.

What are the risks associated with Pegasys?

The most common side effects with Pegasys (seen in more than 1 patient in 10) are loss of appetite, headache, insomnia (difficulty sleeping), irritability, gut disorders (diarrhoea, nausea, and belly ache) rash, itching, hair loss, pain in muscles and joints, flu-like illness, reactions at the site of the injection and tiredness. For the full list of all side effects reported with Pegasys, see the package leaflet.

Pegasys must not be used in people who are hypersensitive (allergic) to alpha interferons or any of the other ingredients. Pegasys must also not be used in patients with certain liver, heart and other conditions. For the full list of restrictions with Pegasys, see the package leaflet.

Why is Pegasys approved?

Studies showed that Pegasys is effective at clearing signs of viral infection in adults and children with chronic hepatitis B or C. The European Medicines Agency (EMA) considered the benefits to outweigh the risks seen with this medicine and therefore recommended that it be given marketing authorisation.

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

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

Other information about Pegasys

The European Commission granted a marketing authorisation valid throughout the EU for Pegasys on 20 June 2002.

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

This summary was last updated in 12-2017.