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SCIENCE MEDICINES HEALTH

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Pegasys (*peginterferon alfa-2a*)

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

What is Pegasys and what is it used for?

Pegasys is a medicine used to treat chronic (long-term) hepatitis B in adults and children from 3 years of age and 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 on its own for hepatitis B infection but is taken in combination with other medicines for hepatitis C.

Pegasys is also used on its own to treat adults with polycythaemia vera (a disease in which the body produces too many red blood cells, which can cause the blood to thicken and reduce blood flow to the organs) and essential thrombocythemia (a disease in which there are too many platelets in the blood).

Pegasys contains the active substance peginterferon alfa-2a.

How is Pegasys used?

Pegasys can only be obtained with a prescription and treatment should be started by a doctor who has experience in the treatment of polycythaemia vera, essential thrombocythemia, or hepatitis B or C.

Pegasys is given by injection under the skin in the abdomen (belly) or thigh, once a week.

Pegasys is available as vials and as pre-filled syringes; the pre-filled-syringes are only to be used for the treatment of polycythaemia vera and essential thrombocythemia. Patients or their carers can inject Pegasys themselves using the pre-filled syringe once they have been trained on how to do so.

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

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,

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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works). Alfa interferons may also block the multiplication of viruses. In polycythaemia vera and essential thrombocythemia, peginterferon alfa-2a is thought to regulate the production of blood cells.

Peginterferon alfa-2a is similar to interferon alfa-2a. 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?

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.

Polycythaemia vera and essential thrombocythemia

Data from three published studies showed that Pegasys is effective at reducing levels of red blood cells or platelets and disease symptoms in adults with polycythaemia vera or essential thrombocythemia.

One study involving 115 patients showed that after 12 months of treatment with Pegasys, 60% of patients with polycythaemia vera and 69% of patients with essential thrombocythemia had a complete or partial response (meaning that their blood cell counts were within a normal range, or reduced by a certain amount, with no disease symptoms). The study did not compare Pegasys with another medicine or placebo (a dummy treatment). Another study in 168 patients showed that 35% of those treated with Pegasys had a complete response after 12 months, compared with 37% of patients receiving another medicine, hydroxyurea. A third study in 83 patients showed that after an average of

69 months of treatment, 80% of patients responded to treatment with Pegasys; the response lasted on average for 66 months.

Additional data, including from another published study, supported the safety of Pegasys when used to treat these conditions.

What are the risks associated with Pegasys?

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

The most common side effects with Pegasys (which may affect more than 1 patient in 10) include loss of appetite, depression, anxiety, headache, insomnia (difficulty sleeping), difficulty concentrating, dizziness, cough, difficulty breathing, irritability, fever, gut disorders (diarrhoea, nausea, and belly pain) rash, itching, dry skin, hair loss, pain in muscles and joints, reactions at the site of the injection and tiredness.

Severe psychiatric side effects, in particular depression, thoughts of committing suicide and attempted suicide, have been observed in some patients during treatment with Pegasys, and even after stopping treatment (mainly during the first six months of follow-up). Other side effects including aggressive behaviour, bipolar disorder, mania (mental disorder with extreme excitement and overactivity), confusion and alterations of mental status have been observed with alfa interferons. All patients treated with Pegasys should be closely monitored for any signs or symptoms of psychiatric disorders.

Pegasys may slow down growth and development in children and adolescents; to reduce this risk, children should be treated with Pegasys after puberty, whenever possible.

Pegasys must not be used together with telbivudine, another medicine used to treat hepatitis B. Pegasys must also not be used in patients with certain liver, heart and other conditions (including autoimmune conditions), and in patients with uncontrolled thyroid disease. Because Pegasys contains benzyl alcohol, it must not be used in neonates and young children up to 3 years of age. Pegasys must also not be used in children with past or present severe psychiatric conditions (in particular severe depression, thoughts of committing suicide or suicide attempt).

Why is Pegasys authorised in the EU?

Studies showed that Pegasys is effective at clearing signs of viral infection in adults and children with chronic hepatitis B or C. Data from published studies also support the use of Pegasys in the treatment of polycythaemia vera and essential thrombocythemia. The safety profile of the medicine is also considered acceptable.

The European Medicines Agency therefore decided that Pegasys'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 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.

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

Other information about Pegasys

Pegasys received a marketing authorisation valid throughout the EU on 20 June 2002.

Further information on Pegasys can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/pegasys.

This overview was last updated in 07-2024.