27 June 2024
EMA/CHMP/145669/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Pegasys

peginterferon alfa-2a

On 27 June 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Pegasys. The marketing authorisation holder for this medicinal product is pharmaand GmbH.

Pegasys is available as a solution for injection and as a solution for injection in pre-filled syringes. The CHMP adopted extensions to the existing indications for the pre-filled syringes to include treatment of polycythaemia vera and essential thrombocythaemia.

For information, the full indications for Pegasys solution for injection in pre-filled syringes will be as follows:[2]

Polycythaemia vera

Pegasys is indicated as monotherapy in adults for the treatment of polycythaemia vera.

Essential thrombocythaemia

Pegasys is indicated as monotherapy in adults for the treatment of essential thrombocythaemia.

Chronic hepatitis B

Adult patients: Pegasys is indicated for the treatment of hepatitis B envelope antigen (HBeAg)-positive or HBeAg-negative chronic hepatitis B (CHB) in adult patients with compensated liver disease and evidence of viral replication, increased alanine aminotransferase (ALT) and histologically verified liver inflammation and/or fibrosis (see sections 4.4 and 5.1).

Paediatric patients 3 years of age and older: Pegasys is indicated for the treatment of HBeAg-positive CHB in non-cirrhotic children and adolescents 3 years of age and older with evidence of

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

viral replication and persistently elevated serum ALT levels. With respect to the decision to initiate treatment in paediatric patients see sections 4.2, 4.4 and 5.1.

Chronic hepatitis C

Adult patients: Pegasys is indicated in combination with other medicinal products, for the treatment of chronic hepatitis C (CHC) in patients with compensated liver disease (see sections 4.2, 4.4 and 5.1). For hepatitis C virus (HCV) genotype specific activity, see sections 4.2 and 5.1.

Paediatric patients 5 years of age and older: Pegasys in combination with ribavirin is indicated for the treatment of CHC in treatment-naïve children and adolescents 5 years of age and older who are positive for serum HCV-RNA.

When deciding to initiate treatment in childhood, it is important to consider growth inhibition induced by combination therapy. The reversibility of growth inhibition is uncertain. The decision to treat should be made on a case by case basis (see section 4.4).

The indications for Pegasys solution for injection have not changed.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.