

**DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION
AGREED WITH AGENZIA ITALIANA DEL FARMACO (AIFA)**

4 November 2024

Pegasys® (peginterferon alfa-2a): supply shortage of 90/135/180 micrograms solution for injection in pre-filled syringes

Dear Healthcare Professional,

pharmaand GmbH and its affiliates (pharma&) in agreement with the European Medicines Agency and the Agenzia Italiana del Farmaco (AIFA) would like to inform you of the following:

Summary:

- **Increased overall demand for Pegasys (peginterferon alfa-2a) has led to an intermittent shortage of all approved strengths (90/135/180 micrograms) of Pegasys. The supply shortage is not related to a quality defect of the product or a safety issue.**
- **pharma& anticipates the shortage to last until the second half of 2025; additional product is currently estimated to be supplied before June 30, 2025.**
- **During the supply shortage prescribers are advised to follow the below recommendations:**
 - **No new patients should be started on Pegasys until supply has normalised. Available product should only be used to continue treatment of patients currently treated.**
 - **In case Pegasys is not available for patients currently under treatment, alternative treatment options should be considered based on your clinical judgement.**
 - **Always store supplies in the fridge and use the most appropriate strength to avoid wastage.**

Background

Pegasys is approved for the following indications:

Pegasys is approved for chronic hepatitis B and C in adults and children, Polycythaemia Vera and Essential Thrombocythemia in adults.

Please refer to the Summary of Product Characteristics par. 4.1 for the full indications.

Suspected Adverse drug reactions reporting

Adverse events including medication errors relating to Pegasys should be reported to pharma& Agenzia Italiana del Farmaco (AIFA) via the following link:

<https://www.aifa.gov.it/web/guest/content/segnalazioni-reazioni-avverse>

Company contact point

Further information can be obtained by contacting pharma&: medinfo@pharmaand.com

AIFA takes this opportunity to remind all Healthcare Professionals of the importance of reporting suspected adverse drug reactions as an indispensable tool for confirming a favorable benefit/risk ratio under actual conditions of use. Reports of Suspected Adverse Drug Reactions should be sent to the Pharmacovigilance Manager of the Facility to which the Practitioner belongs. This Information Note is also published on the AIFA website (<https://www.aifa.gov.it/web/guest>) whose regular consultation is recommended for the best professional information and service to citizens