**Importation of Irish-labelled PEGASYS® due to the current shortage of Canadian-authorized PEGASYS® (peginterferon alfa-2a injection)**
**DIN 02248077**

pharmaand GmbH
Taborstrasse 1
1020 Vienna
Austria

25 June 2025

Dear Healthcare Professionals and Wholesalers,

There is a critical shortage of PEGASYS® (peginterferon alfa-2a injection) in Canada. To help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation, and sale of pharmaand GmbH's Irish-labelled PEGASYS® by Accelera Pharma Canada Inc (APCI), the Canadian Importer and Distributor of PEGASYS®.

Health Canada has accepted the addition of pharmaand GmbH's product to the List of drugs for exceptional importation and sale.

In Canada, PEGASYS® is indicated for:

**Chronic Hepatitis C (CHC)**
PEGASYS (peginterferon alfa-2a) is indicated for the treatment of Chronic Hepatitis C in:

- Adult patients without cirrhosis
- Adult patients with compensated cirrhosis

including HCV/HIV co-infection patients with stable HIV disease with or without antiretroviral therapy.

**Chronic Hepatitis B (CHB)**
PEGASYS is indicated for the treatment of both HBeAg-positive and HBeAg-negative chronic hepatitis B in:

- Patients with compensated liver disease, liver inflammation and evidence of viral replication (both cirrhotic and non-cirrhotic disease).

**Geriatrics (> 65 years of age)**: Clinical studies of PEGASYS alone or in combination with COPEGUS did not include sufficient numbers of subjects aged 65 or over to determine whether they respond differently from younger subjects.

**Pediatrics (< 18 years of age):** PEGASYS is not authorized for use in children and adolescents under the age of 18 years (see WARNINGS AND PRECAUTIONS: Special Populations, Pediatrics).

Health Canada is aware that there is 'off-label' use of PEGASYS® in Canada and is therefore directing Health Care Professionals to the European approved Summary of Product Characteristics (SmPC) provided below for dosing, clinical efficacy and safety information relevant to the treatment of polycythaemia vera (PV) and essential thrombocythaemia (ET). Health Canada further recommends that Health Care Professionals refer to institutional guidelines for guidance on dose adjustment in the context of adverse events, when treating PV/ET.

Healthcare Professionals should refer to the Canadian Product Monograph for PEGASYS® available in English and French on the APCI website at this link: https://apcipharma.com/produit/pegasys/, or the Health Canada Drug Product Database at https://health-products.canada.ca/dpd-bdpp/. The Product Monograph contains more comprehensive information than the corresponding sections of the SmPC for information on:

- contraindications
- warnings and precautions

**The Irish-labelled product has the same formulation, strength, presentation and quality specifications as the Canadian-authorized product. The Irish-labelled PEGASYS® can be used in the same manner as the Canadian-authorized PEGASYS®.**

The Irish-labelled product, however, **differs** in the following ways: the Irish PEGASYS® syringe is packed in a 4-syringe tamper evident sealed carton instead of the single syringe Canadian presentation.

**INFORMATION ABOUT THE IMPORTED PRODUCT**

- Brand Name: PEGASYS®
- Country of authorization and identifying code: Ireland, EU
- Authorization Holder: pharmaand GmbH
- DEL holder/ importer in Canada: Accelera Pharma Canada Inc. (APCI)
- The Irish-labelled product has the **same** formulation, strength, presentation and quality
- **Each 0.5 mL of PEGASYS® contains 5.0 mg benzyl alcohol**

| **Dosage form, strength and route of administration** | **Product description and packaging** |
|---|---|
| Pre-filled syringes<br><br>180 mcg/0.5 mL sterile solution for subcutaneous injection.<br>Syringes must be stored in the refrigerator at 2-8°C. | PEGASYS® is a sterile, ready-to-use solution for subcutaneous injection. Each 0.5mL contains 180 mcg of peginterferon alfa-2a (expressed as the amount of interferon alfa-2a), 4.0 mg sodium chloride, 0.025 mg polysorbate 80, 5.0 mg |

| | |
|---|---|
| Do not freeze PEGASYS®.<br><br>Do not shake PEGASYS®.<br><br>Protect from light during storage.<br><br>Keep out of reach of children. | benzyl alcohol, 1.3085 mg sodium acetate trihydrate, 0.0231 mg acetic acid and water for injection, at pH 6 ± 0.2.<br><br>Available in single-use, graduated, clear glass pre-filled syringes in **cartons of 4.** |

The Health Canada approved Package Insert will also be supplied with each carton. An image of the Irish PEGASYS® carton and syringe label can be found in the Appendix below.

Healthcare Professionals are advised that aspects of the inner and outer labels and packaging of the Irish-labelled product may differ from marketed PEGASYS® in Canada. **Proper selection of the intended product must be verified to avoid confusion with other products and prevent medication errors.**

**REPORTING ADVERSE DRUG REACTIONS**
Adverse drug reactions associated with the use of PEGASYS® should be reported to APCI by calling 1 855 611-2724 or to Health Canada by calling toll-free at 1-866-234-2345.

**QUESTIONS OR CONCERNS**
For questions or concerns about Irish-labelled PEGASYS® please contact APCI by calling 1 855 611-2724.

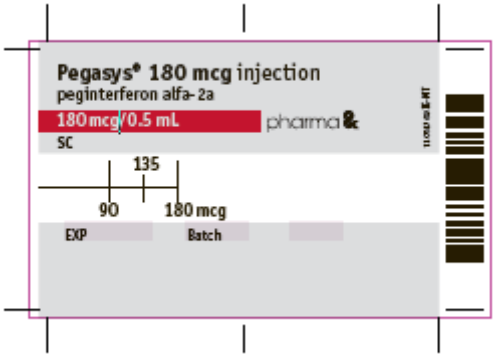
Imported and Distributed by Accelera Pharma Canada Inc. (APCI)
3278 South Service Road West, Unit #5
Oakville, Ontario L6L 0B1

Sincerely,

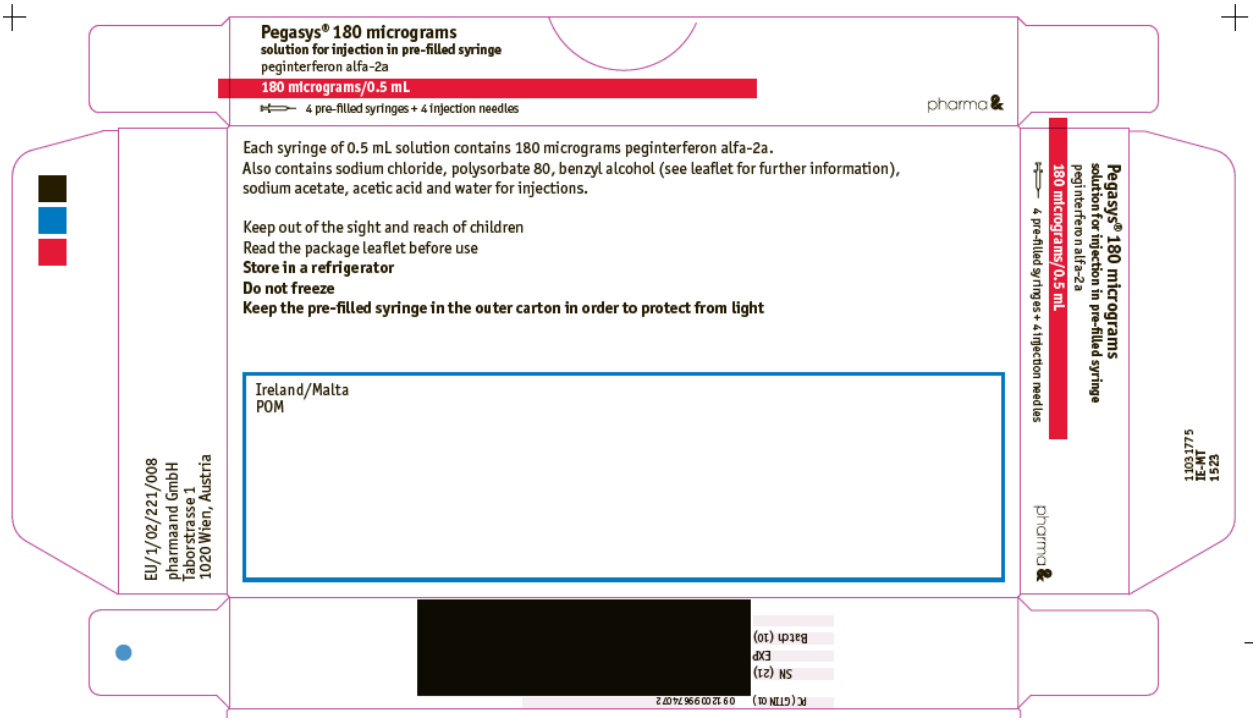
Kaustav Chatterjee
Vice President, Commercial Operations
pharmaand GmbH

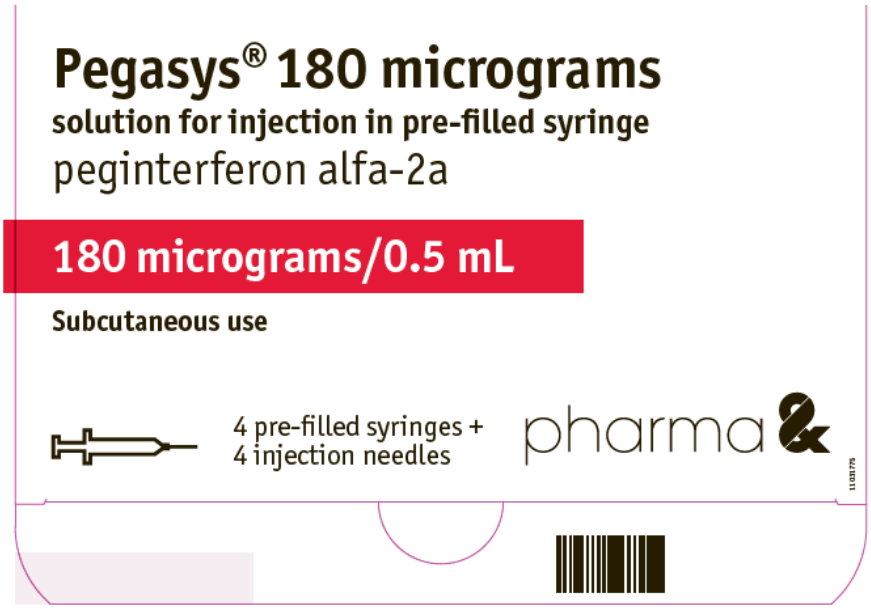
**APPENDIX 1**

Irish PEGASYS® syringe label:

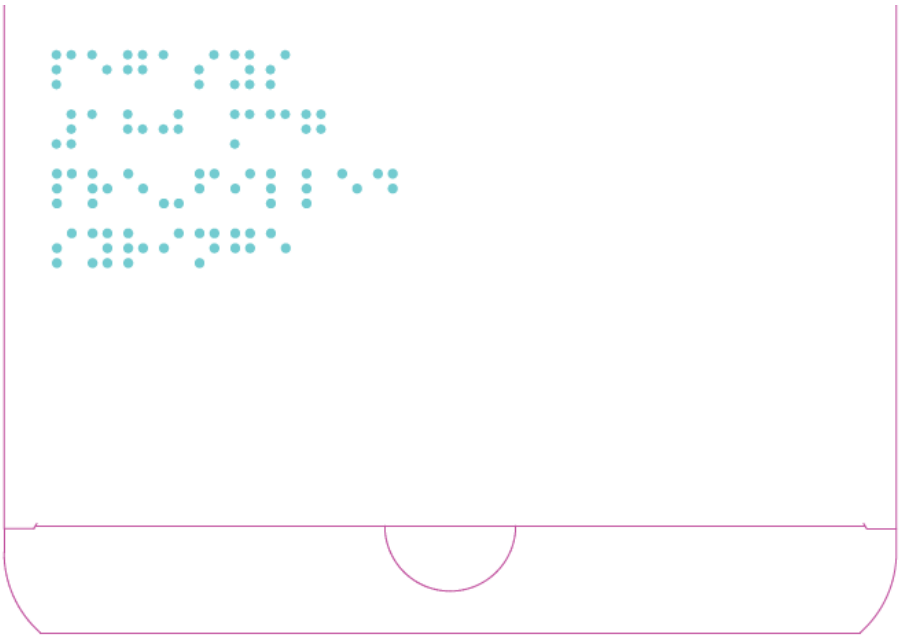



Irish PEGASYS® carton label:






The carton includes braille as follows:



pharmaand GmbH
Taborstrasse 1, 1020 Vienna, Austria

**APPENDIX 2**

EMA APPROVED ENGLISH SMPC

https://apcipharma.com/wp-content/uploads/2025/06/EMA-SmPC-EN-Pegasys-INN-peginterferon-alfa-2a.pdf