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Date: 22nd November 2022

**DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION**

**Discontinuation of Fragmin (Dalteparin Sodium) 10,000IU/1 ml ampoule (PL 00057/977)**

Dear Healthcare Professional,

Pfizer Limited would like to inform you of the discontinuation of the Fragmin 10,000IU/1 ml ampoule presentation in the first quarter of 2023.

**Summary**
A very limited quantity of the UK registered product is still available to the market. In order to minimise disruption from discontinuation of this product, Pfizer has obtained agreement from the Medicines and Healthcare products Regulatory Agency (MHRA) to import under special authorization of importation stock of Fragmin 10,000IU/1 ml ampoule from Canada. This measure is to provide additional stock over the next 5 months to allow safe transition to alternative options.

Pfizer will continue to supply the licensed 10,000IU/1 ml graduated prefilled syringe, and all the other currently approved presentations in the UK

**Please note the following:**

- The Canadian imported product (Batch # FR1480, Exp. November 2024) is supplied under a Batch Specific Variation to the UK Product Licence approved by the MHRA.
- The Marketing Authorisation Holder stated on the pack for the Canada product is Pfizer Canada ULC.
- The contact details below should be used for any enquires or Adverse Event reporting.
- The Canadian product is manufactured at the same manufacturing site and has the same formulation as the UK product.
- The prescribing information at the Canadian Product Monograph is identical to the Summary of the UK Product Characteristics.
- There are minor differences between the two Carton and Container Labeling with no consequences on the overall benefit-risk profile of the product. For ease of reference, please see a representation of the UK authorised pack and the imported Canadian pack:

Figure 1: Licensed UK product carton – Fragmin 10,000IU/1 ml ampoule PL 00057/977

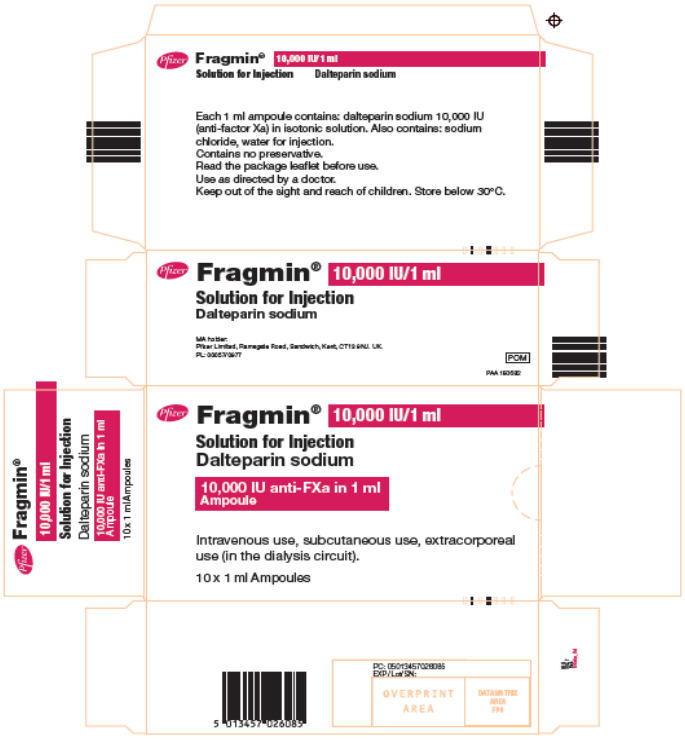
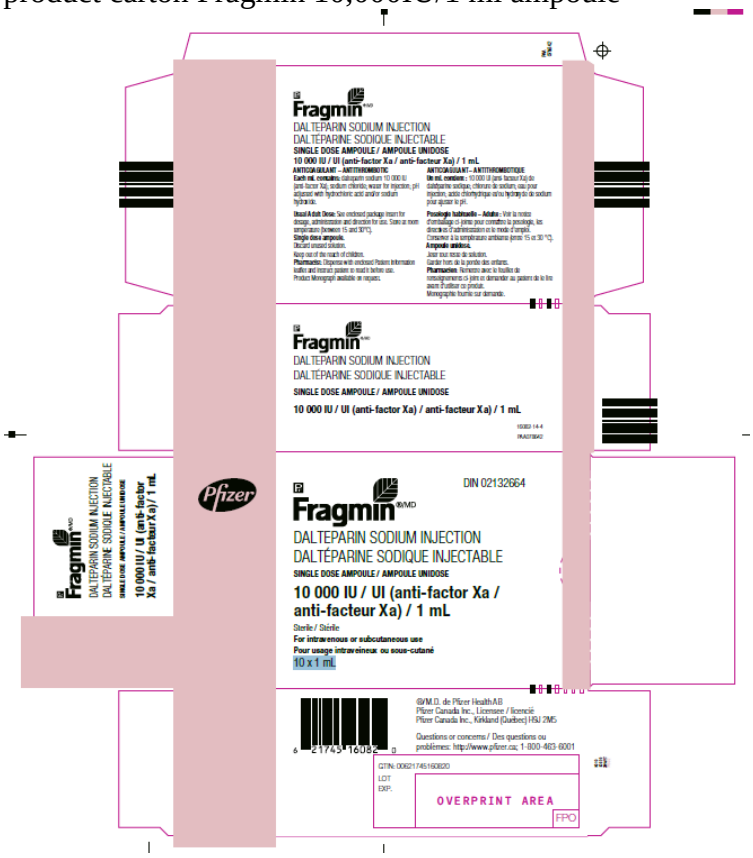



Figure 2: Canada product carton Fragmin 10,000IU/1 ml ampoule



**Further information**
Fragmin 10,000 IU/1 mL ampoule is indicated for use in adults for:

- Prevention of clotting in the extracorporeal circulation during haemodialysis or haemofiltration, in patients with chronic renal insufficiency or acute renal failure.
- Treatment of venous thromboembolism (VTE) presenting clinically as deep vein thrombosis (DVT), pulmonary embolism (PE) or both.
- Unstable angina and non-Q wave myocardial infarction (unstable coronary artery disease-UCAD), administered concurrently with aspirin.

Please refer to the Summary of UK Product Characteristics (SPC) for further details.
Links to eMC website: https://www.medicines.org.uk/emc/product/4251

**Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.**

**Call for reporting**
You can assist us with monitoring the safety of by reporting suspected adverse reactions. Suspected adverse drug reactions (ADRs) should be reported to MHRA through the Yellow Card Scheme online at www.mhra.gov.uk/yellowcard. Alternatively, prepaid Yellow Cards for reporting are available:

- upon request by mail: "FREEPOST YELLOW CARD"
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- or by electronic download through the Yellow Card section of the MHRA website.

Suspected adverse drug reactions may also be reported to Pfizer Medical Information on 01304 616161.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

**Company contact point**
If you have any questions about this letter or for more information about Fragmin, please contact Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or Telephone: 01304 616 161.

Yours Faithfully,

DocuSigned by:
Samantha Howland
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Samantha Howland
Senior Medical Director
Hospital and IDM Business Unit
Pfizer Ltd