Swedish Orphan Biovitrum Ltd
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Great Abington, Cambridgeshire, CB21 6AD
Web site: https://www.sobi.com/uk/en

23 January 2025

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Kineret® (anakinra) 100 mg solution for injection in a pre-filled syringe:
Interim Supply of foreign packs to mitigate supply disruption of UK packs (PLGB 30941/0018)

Dear Healthcare Professional,

Summary: Sobi UK is currently experiencing supply disruption with Kineret® (anakinra) 100 mg solution for injection in a pre-filled syringe in the UK (Great Britain).

To ensure continuity of supply, Sobi UK has obtained approval from the MHRA to supply the same product from markets outside the UK (Denmark/Norway/Sweden/Finland/Iceland shared pack; Greece/Cyprus shared pack; France/Netherlands shared pack; Spain/Croatia/Hungary/Slovenia shared pack) for a duration of 4 weeks, until the end of February 2025.

It is expected that provision of anakinra via UK stock will resume by the third week of February 2025.

Please note the following:

- The products are considered licensed in the UK.
- The EU packs to be supplied have the same formulation as the UK product.
- The EU packs are manufactured according to the same manufacturing process and quality controls as the UK product.
- There are language differences between the EU packs (non-English language) and the UK packs – a hard copy of the UK Patient Information Leaflet (PIL) will be provided.
- Please ensure that your patients refer to the UK approved PIL supplied with each order of the foreign packs and discard the non-English language leaflet in the original packs.
- Please ensure that the UK Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) are followed.
- For additional copies of the leaflet, please refer to https://www.medicines.org.uk/emc/files/pil.559.pdf or contact Sobi UK (see below for Company contact point).
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Kineret® (anakinra) and that the information must be provided in English.

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

Relevant batch numbers and expiry dates for each EU country cluster pack to be supplied:

Countries	Batch Number(s)	Expiry date(s)
Denmark/Norway/Sweden/Finland/Iceland shared packs	4177301B	31-May- 2027
Greece/Cyprus shared pack	4151301B	30-Apr-2027
France/Netherlands shared pack	4116503B 4199101A	31-Jan-2027 31-Aug-2027
Spain/Croatia/Hungary/Slovenia shared pack	4151201A, 4151401C and 4151401D	30-Apr-2027

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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

Company contact point
If you have any questions about this letter or require more information about Kineret® (anakinra), please contact Sobi UK & Ireland Medical Information via email at medical.info.uk@sobi.com or by calling +44 (0) 800 111 4754.

Yours faithfully,

Signed by:
Jonathan Loukes
Signer Name: Jonathan Loukes
Signing Reason: I approve this document
Signing Time: January 24, 2025 | 09:03:32 CET
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