

Date: 30 January 2023

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

**Amvuttra 25mg solution for injection in pre-filled syringe (vutrisiran):
Interim Supply of German Stock to Enable Early Treatment Prior to Availability of UK (NI)
Commercial Stock**

Dear Healthcare Professional,

Summary: Alnylam B.V. Netherlands is temporarily supplying German packs of Amvuttra 25mg solution for injection in pre-filled syringe (vutrisiran) in the UK (NI) to enable early treatment prior to availability of UK (NI) commercial stock.

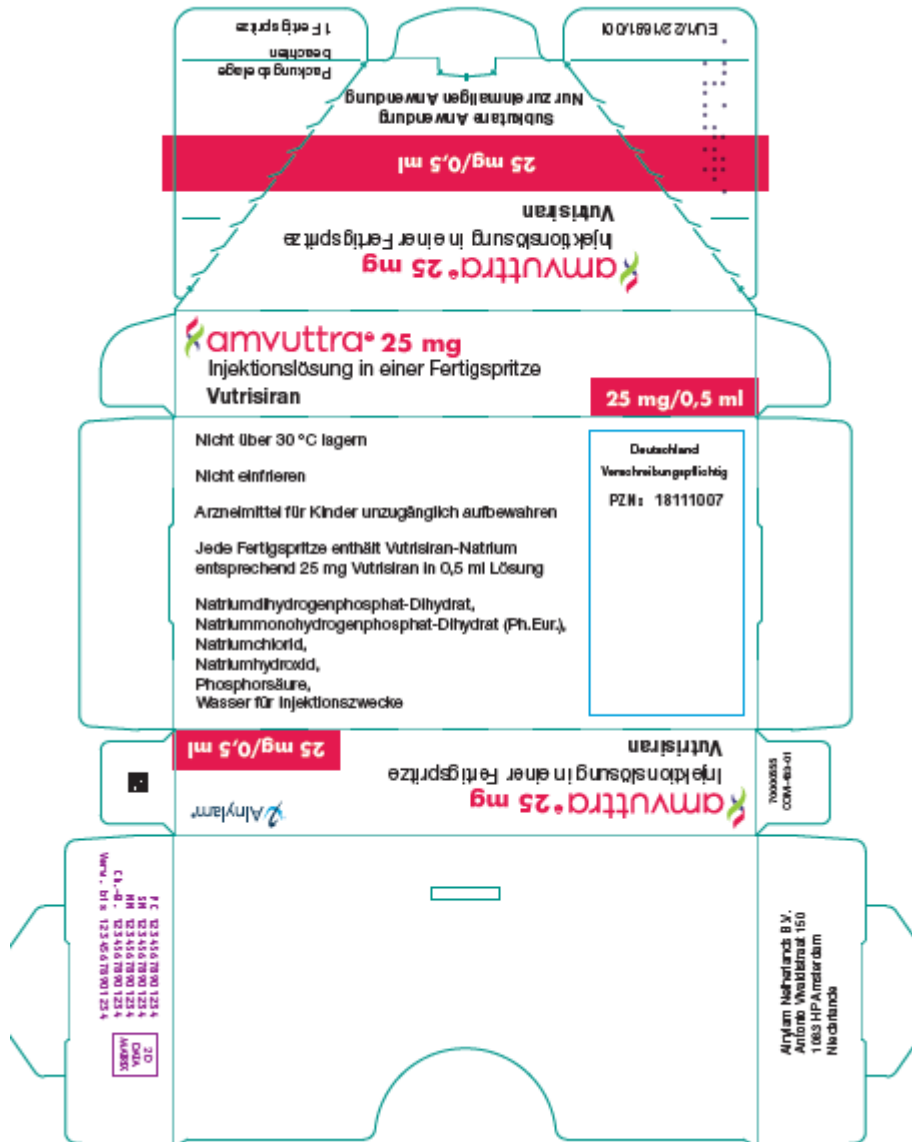
Alnylam B.V. Netherlands has obtained approval from the MHRA to supply German product (batch number 650313; batch size 280 packs), which is expected to be on the UK market from 23 February 2023 to 31 May 2023.

Please note the following:

- This product is considered licensed in the UK (Northern Ireland).
- The product from Germany has the same formulation as the UK (Northern Ireland) product.
- The product from Germany is manufactured according to the same manufacturing process and quality controls as the UK(NI) product.
- Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- Please refer to the UK approved SPC and PIL supplied electronically with the German packs. Discard the German leaflet in the pack.
- For additional copies of the leaflet, please refer to <https://www.medicines.org.uk/emc/> for UK, Great Britain, [emc northern ireland \(emcmedicines.com\)](https://www.medicines.org.uk/emc/) for UK, Northern Ireland or contact the company contact point (see below).
- The MHRA has agreed to an exemption according to Article 63(3) of Council Directive 2001/83/EC, from the obligation that certain particulars should appear on the outer and immediate packaging of Amvuttra and that the information must be given in English.

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

An image of the carton box of the imported product in German packaging is provided below for reference.



Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <https://yellowcard.mhra.gov.uk/>, the free Yellow Card app available from the [Apple App Store](#) or [Google Play Store](#), and some clinical IT systems (EMIS, SystemOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

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



This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. Refer to section 4.8 of the Summary of Product Characteristics for how to report adverse reactions.

Company contact point

If you have any questions about this letter or require more information about Amvuttra, please contact Alnylam Medical Information at medinfo@alnylam.com or telephone +44 (0) 1628878592.

Yours faithfully,

[Signature]

DocuSigned by:
Phil Davey
Signer Name: Phil Davey
Signing Reason: I approve this document as Alnylam Executive Leadership Member
Signing Time: 30-Jan-2023 | 12:59 PM EST
A45A11E9B79441DD9932EED50A406646
Phillip Davey
UK & Ireland Country Manager

Alnylam UK Ltd

[Signature]

DocuSigned by:
(Dora Kan)
Signer Name: Dora Kan
Signing Reason: I approve this document as Alnylam C
Signing Time: 31-Jan-2023 | 4:35 AM GMT
866DF302A5C24B008C2BBF3FBC290561
Dora Kan
Quality Assurance
Responsible Person

Alnylam UK Ltd