Date: January 2024

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Artiss 2ml Fibrin Sealant [Human] (product code: 5500649)
Interim supply of Nordic Stock (Norway/Denmark) to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary

Baxter Healthcare Ltd is currently experiencing supply disruption with Artiss 2ml Fibrin Sealant [Human], in the UK. Artiss is indicated as a tissue glue to adhere/seal subcutaneous tissue in plastic, reconstructive and burn surgery, as a replacement or an adjunct to sutures or staples. In addition, Artiss is indicated as an adjunct to haemostasis on subcutaneous tissue surfaces.

To ensure continuity in supply during the period of disruption, Baxter has obtained approval from the Medicines and Healthcare Products Regulatory Agency (MHRA) to supply Nordic product D9Z004AB and D9Z006AD, two batches containing 240 units in total which are expected to be available on the market from December 2023 to February 2024.

Please note the following:

- This product is considered licensed in the UK.
- The product from Norway/Denmark has the same formulation as the UK product.
- The product from Norway/Denmark is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are language differences on the packaging and also in the product information leaflet (PIL) as shown in the below images. Please be aware that the Norway/Denmark product is stored and used in the same manner as the UK 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 with the current United Kingdom packs of Artiss or, if these are not available, use the below QR codes and links to access additional copies.
- The MHRA has approved this product under a batch specific variation to the marketing authorisation.

Please ensure all relevant staff are made aware of the content of this letter.

Baxter Healthcare Ltd
Caxton Way / Thetford / Norfolk / IP24 3SE / Great Britain
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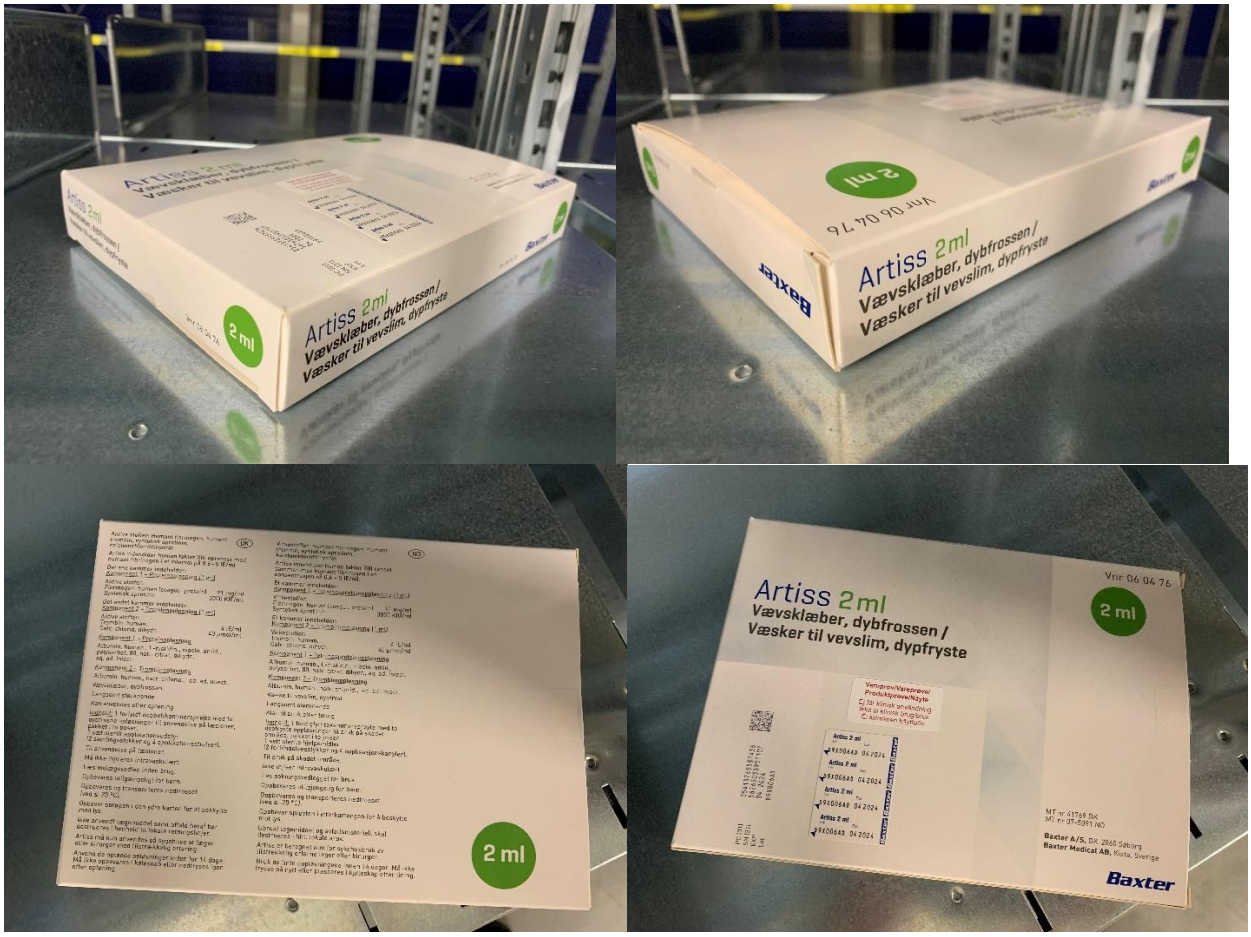
Registered Office: Caxton Way / Thetford / Norfolk / IP24 3SE Registered in England No. 461365

Images of imported product
(Note that the labelling is the same; the only differences are the language)



A copy of the UK Artiss SPC and UK Product Information Leaflet (PIL) will be included with every shipment of the product.

Please Scan the below QR code or click on the link to access the Artiss SPC

https://vablet.com/s/emEBjmg

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Please Scan the below QR code or click on the link to access the Artiss product information leaflet (PIL)

https://vablet.com/s/LjZpv61

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 clinical questions about the information contained in this letter, or the use of Artiss, please contact Baxter Medical Information on 01635 206345 or email medinfo_uki@baxter.com.

Kind Regards

Aaron Dallimore
Advanced Surgery Marketing and Business Transformation Lead
Baxter Healthcare Ltd