Direct Healthcare Professional Communication

Vyxeos (cytarabine, daunorubicin): temporary interruption of UK packaging

Date: 01 March 2019

Dear Healthcare Professional:

With agreement from the Medicines and Healthcare products Regulatory Agency (MHRA), Jazz Pharmaceuticals would like to inform you of the following:

Summary

- Jazz Pharmaceuticals is experiencing an interruption of 8 to 10 days of supply for Vyxeos packs labelled and packaged in English language; we expect supply to resume on 15 March 2019
- In the interim, we have obtained approval from the Medicines and Health Care Regulatory Agency (MHRA) on 28 February 2019 to temporarily supply UK requests for Vyxeos by **providing Nordic packs, containing Nordic-language leaflets.**
- Vyxeos has a single marketing authorisation throughout the European Union. Packs with Nordic language labelling and package leaflets contain the same Vyxeos drug product as packs labelled for the UK market.
- Although Nordic packs are labelled and packaged with a patient information leaflet in the Nordic language, a UK patient information leaflet will also be attached to the pack (a copy is enclosed with this letter) and include instructions for the reconstitution of the product.
- As the Nordic packs will only be supplied with the additional UK patient information leaflet and letter and to be dispatched when an individual patient order is received, any Nordic stocks to be held in hospital pharmacies or in the supply chain should not be expected once the UK packs become available.
- The Summary of Product Characteristics in English is available on the Jazz Pharmaceuticals website: https://www.jazzpharma.com/medicines/our-medicines/.

Important information to note from the labelling text is:

- Each vial contains 44 mg of daunorubicin and 100 mg of cytarabine.
- After reconstitution the solution contains 2.2 mg/mL daunorubicin and 5 mg/mL cytarabine encapsulated in liposomes
- The product is for intravenous use after dilution.
- The products should be stored in a refrigerator.
- Keep the vial in the outer carton in order to protect from light.
- Store the product in an upright position.

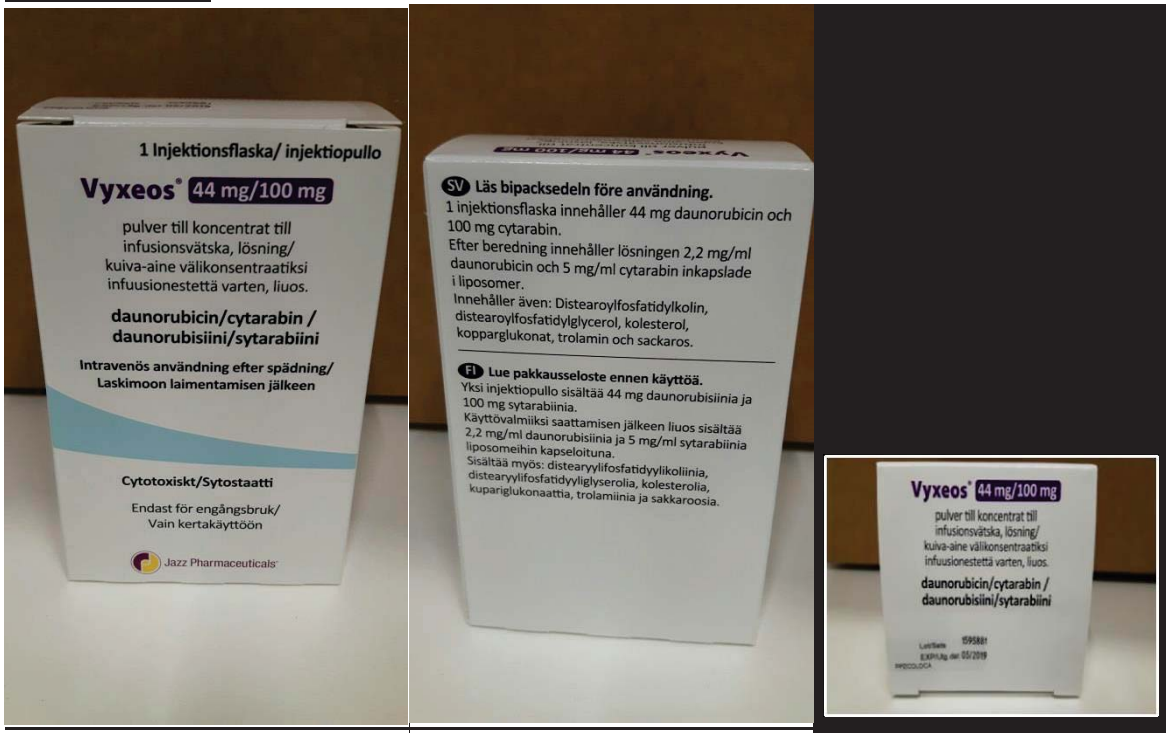
Details of the batches of Vyxeos to be supplied in Nordic livery during the UK livery out of stock period are as follows:

- The batch number for Vyxeos livery Sweden/Finland is 1595881; 1 vial per pack; expiry date is May 2019.

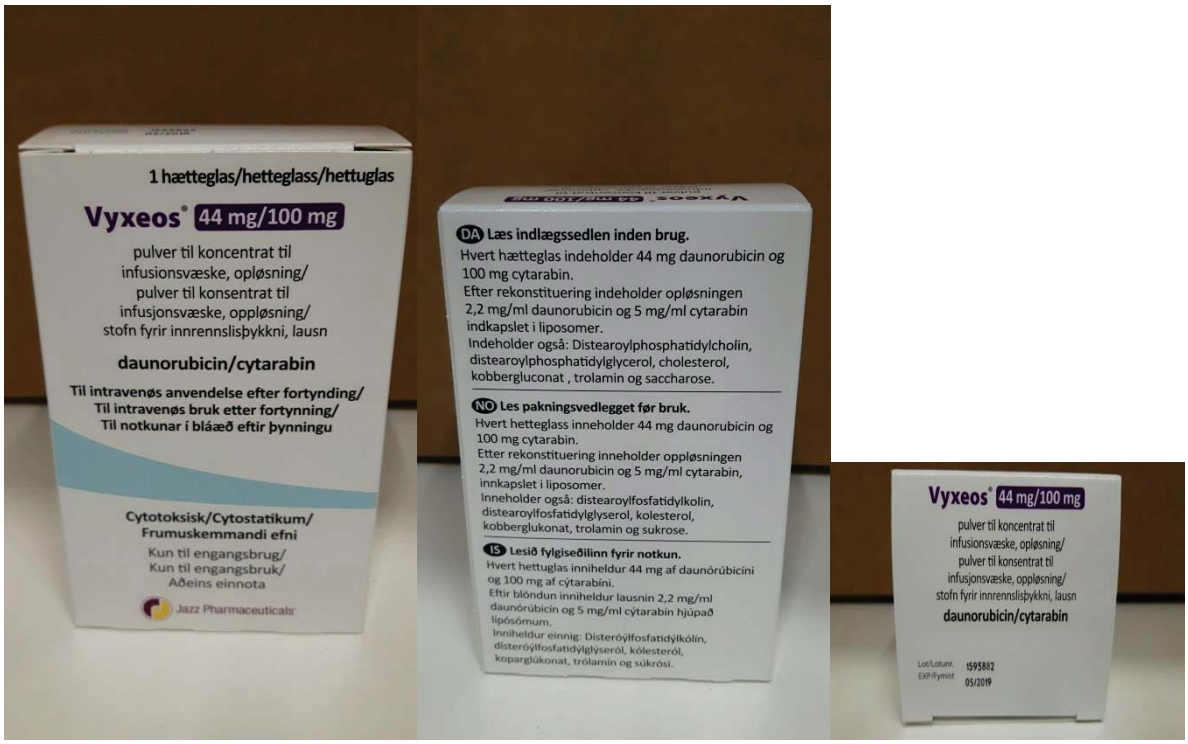
- The batch number for Vyxeos livery Denmark/Norway/Iceland is 1595882; 1 vial per pack; expiry date is May 2019.

Pictures of the Nordics packs

Batch 1595881:



Batch 1595882:



Background
Vyxeos is indicated for adult patients with newly diagnosed, therapy-related acute myeloid leukaemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).

We will notify you of any relevant updates should this be required, as and when agreed with the MHRA.

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 ▼

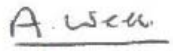
It is easiest and quickest to report ADRs online via the Yellow Cards website https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

Alternatively, prepaid Yellow Cards for reporting are available:
- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- 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 downloading and printing a form

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 any other enquiry, please contact Medical Information at the following address:
Tel +44 (0)845 0305089
medinfo-uk@jazzpharma.com

Yours sincerely,



Dr. Andrew Webb
Medical Director
Jazz Pharmaceuticals