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Worldwide Biopharmaceutical Businesses

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Ecalta 100mg Powder for Concentrate for Solution for Infusion (Anidulafungin): Solution for Infusion must no longer be frozen

Dear Healthcare Professional,

Pfizer Europe MA EEIG in agreement with the European Medicines Agency (EMA) and Medicines and Healthcare products Regulatory Agency (MHRA), Pfizer limited, would like to inform you of the following:

SUMMARY

- The current product information for Ecalta (active substance anidulafungin) allows freezing of the (reconstituted) infusion solution but recent study findings concluded by the manufacturer indicate that this storage condition requires revision. Freezing the product may lead to the formation of visible particles due to the lack of solubility of the Ecalta drug substance (anidulafungin) in the infusion solution following storage at freezer conditions and subsequently thawed.
- **Instructions to health care professionals:** In contrast to what is stated in the current version of the product information, **the (reconstituted) infusion solution should not be frozen. The infusion solution may be stored at 25ºC for 48 hours.**
- The product information of Ecalta will be updated shortly to include the correct instructions.

FURTHER INFORMATION ON THE SAFETY CONCERN AND THE RECOMMENDATIONS

- The revised storage recommendation is based on an infusion study that was initiated for Ecalta to evaluate in-use stability for Ecalta solutions across labelled storage conditions. The study found the infusion solutions were Out of Limit (OOL) for Completeness & Clarity

- USP testing, a test for the presence of visible particles (note that this test is equivalent to the EP Particulate Matter Visible test). In the case of these failures, the infusion solution contained numerous, white, amorphous particles that were very visible after the solution was removed from freezer conditions and brought to room temperature. The visible particles were identified in the infusion solutions at a low rate and only for IV bags that had been frozen. The particulates observed were determined to be anidulafungin, the active substance for Ecalta. There were no other failures for any other testing conducted for this infusion study.

- The **current** Section 6.3 of the Summary of Product Characteristics in the Product Information **incorrectly** states that the infusion solution **can be frozen for up to 72 hrs**. **This advice should not be followed** based on aforementioned reasons.

- The Summary of Product Characteristics also includes the following statement (**which still is correct**): "The solution should be inspected visually for particulate matter and discolouration prior to administration. If either particulate matter or discolouration are identified, discard the solution".

- A search of the post-marketing safety database as for the period 21 February 2017 to 02 December 2019 for anidulafungin identified no safety issues related to OOL for Completeness and Clarity USP testing or presence of visible particulates in anidulafungin IV infusion bags.

- A 5-year complaints history from 27 September 2014 to 27 September 2019 was reviewed and no complaints related to this issue were found.

FURTHER INFORMATION

For further details on the product please refer to the approved UK Summary of Product Characteristics (SPC) and Patient Information Leaflet, which are available on the emc website: www.medicines.org.uk

Therapeutic indication of the medicinal product

Treatment of invasive candidiasis in adult patients.

CALL FOR REPORTING

Please continue to report any suspected adverse drug reactions (ADRs) to the Medicines and 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 Card website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play 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
- by downloading and printing a form from the Yellow Card website (see link above)

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 and treatment dates.

COMPANY CONTACT POINT

Alternatively, suspected adverse reaction may also be reported to the marketing authorisation holders using the details provided below. If you have further questions or require additional information, please contact Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or Telephone: 01304 616 161.

Yours sincerely,

DocuSigned by:
Alicia Sanders
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Alicia Sanders

UK Hosptital Medical Director