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Direct healthcare-professional communication (DHPC)

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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 Saudi Limited in agreement with the Saudi Food and Drug Authority, would like to inform you of the following:

SUMMARY

- A recent study by the manufacturer indicated that freezing the (reconstituted) infusion solution 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: The (reconstituted) infusion solution should <u>not</u> be frozen. The infusion solution should be stored in a refrigerator (2°C - 8°C) and should be administered at 25°C (room temperature) within 24 hours. Do not freeze.**

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.
- 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.

For further information, please refer to Anidulafungin SmPC enclosed.

CALL FOR REPORTING

Please continue to report any suspect adverse drug reactions to the:

1. The National Pharmacovigilance and Drug Safety Centre (NPC):
    - SFDA call center: 19999
    - Toll free phone: 8002490000
    - Fax: +966-11-205-7662
    - E-mail: npc.drug@sfda.gov.sa
    - Website: https://ade.sfda.gov.sa
2. Pharmacovigilance department at Pfizer Saudi Limited:
    - E-mail: SAU.AEReporting@pfizer.com

Yours sincerely,

Ashraf hassanien

Ashraf Hassanien
Senior Medical Manager