



DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy, Retail and Wholesaler Level

Date: 23 July 2020

EL (20)A/32

Our Ref: MDR 135-12/19

Dear Healthcare Professional,

Pfizer Limited

Ecalta 100mg powder for concentrate for solution EU/1/07/416/002
for infusion

Batch Number	Expiry Date	Pack Size
DN 6937	30/09/2022	1 vial
DX 1158	30/09/2022	1 vial

Active pharmaceutical ingredient: anidulafungin

Brief description of the problem

Pfizer Limited has informed us that the packs for the above batches have not been packaged with the current version of the Patient Information Leaflet (PIL) containing updated storage instructions of the infusion solution in section 5.

Section 5 How to store ECALTA

Incorrect information in the PIL of the affected batches	Correct information that should be in the PIL
The reconstituted solution may be stored up to 25°C for up to 24 hours. The infusion solution may be stored at 25°C (room temperature) for 48 hours or stored frozen for at least 72 hours and should be administered at 25°C (room temperature) within 48 hours.	The reconstituted solution may be stored up to 25°C for up to 24 hours. The infusion solution may be stored at 25°C (room temperature) for 48 hours, (do not freeze) and should be administered at 25°C (room temperature) within 48 hours. The section of the PIL for medical or healthcare professionals was also updated to include the following statement: <u>“The infusion solution must not be frozen”.</u>



Advice for healthcare professionals

When dispensing this medicine from the affected batches listed above, please ensure that the correct PIL is issued.

The correct PIL is available from the electronic medicines compendium (EMC) website by clicking on the link below:

[PIL for ECALTA 100mg powder for concentrate for solution for infusion](#)

The Summary of Product Characteristics (SmPC Section 6.3) has been updated to state “The infusion solution may be stored at 25°C for 48 hours. Do not freeze”.

The updated SmPC is available on the EMC website: www.medicines.org.uk

Further Information

For suspected adverse reaction and/or medical information queries, please contact:
Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS
Telephone: 01304 616 161

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

NHS England and NHS Improvement Regional Offices are asked to forward this alert to community pharmacy contractors.

Yours faithfully

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