



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy/Wholesaler Level

Date: 11 February 2021

EL (21)A/03

Our Ref: MDR 053-02/21

Dear Healthcare Professional,

Gilead Sciences Ltd

AmBisome Liposomal 50 mg Powder for dispersion for infusion **PL 16807/0001**

Batch Number	Expiry Date	Pack Size	First Distributed
019364D	31-Aug-23	10 Vials	06-Apr-20
D1900146D	31-Oct-23	10 Vials	27-Apr-20
019545D	30-Nov-23	10 Vials	18-Aug-20
GAD221D	31-Dec-23	10 Vials	30-July-20
020759D	29-Feb-24	10 Vials	14-Sep-20
019547D	30-Nov-23	10 Vials	07-Sep-20
D2000038D	31-Mar-24	10 Vials	26-Oct-20
020570D	31-May-24	10 Vials	20-Jan-21
GAD244D	30-Apr-24	10 Vials	10-Dec-20
020595D	31-Dec-23	10 Vials	07-Oct-20
D2000066D	31-May-24	10 Vials	31-Dec-20
D2000049D	30-Apr-24	10 Vials	08-Dec20

Active Pharmaceutical Ingredients: amphotericin B

Brief description of the problem

Gilead Sciences Ltd has informed us of a quality defect issue, in relation to specific lots of 5µm sterile filters, which are co-packed in cartons of the AmBisome product. The medical device is called Minisart Filter 16534-K. The device manufacturer has informed Gilead that the filter lots packaged with the AmBisome batches listed in this notification may be releasing fibres and particles, which may pose a risk to the patient. **There is no quality issue associated with AmBisome product and due to supply considerations, the product is not being recalled.** Gilead Sciences Ltd have confirmed that no further affected stock will be distributed, whilst they re-package packs with the correct filter. For packs already with wholesalers these will not be distributed onwards, until a replacement filter is provided by Gilead Sciences Ltd, to be provided with the impacted batches at the point of distribution. New filters will be available with packs w/c 15 February 2021.

Advice for healthcare professionals

- Check the existing stock within your possession and identify if any of the AmBisome batches listed above are affected by this issue. Please note that in addition to your pharmacy, this includes clinics, wards and any other relevant locations.



- Open the cartons and remove the defective Minisart filters and ensure you dispose of them appropriately. These filters should not be used.
- Other suitable 5 micron filters may be available in your hospital. Alternatively, as stated under section 6.6 of AmBisome SmPC: “An in-line membrane filter may be used for intravenous infusion of AmBisome. However, the mean pore diameter of the filter should not be less than 1.0 micron”.
- Filters from an alternative supplier are available from Gilead. Please contact your Gilead Customer Services representative at UKCustomer.Services@gilead.com if you require information concerning suitable alternative filters or if you require replacement filters.

Advice for wholesalers

- Stop supplying the above products immediately and put these batches in quarantine.
- Quarantined AmBisome cartons should not be opened at 3PLs/distributors to replace out the defective filters with new filters, but rather for the 3PLs/distributors will be provided with replacement filters, to send with the impacted AmBisome batches.
- Please contact your Gilead Customer Services representative at UKCustomer.Services@gilead.com to arrange for replacement filters.

Further Information

For more information or medical information queries, please contact:

Gilead Sciences Ltd Medical Information

Telephone: +44 (0) 8000 113700

E-mail: ukmedinfo@gilead.com

For stock control queries, please contact:

Customer Care direct line: +44 (0)203 681 4681

E-mail: UKCustomer.Services@gilead.com

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice.

NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574