

## MEDICINES NOTIFICATION

### CLASS 4 MEDICINES INFORMATION

#### Caution in Use

#### Distribute to Pharmacy/Wholesaler Level

Dear Healthcare Professional

### Gilead Sciences Ltd

**PL 16807/0001**

### AmBisome Liposomal 50 mg Powder for dispersion for infusion

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](mailto: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](mailto: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](mailto:ukmedinfo@gilead.com)

For stock control queries, please contact:  
Customer Care direct line: +44 (0)203 681 4681  
E-mail: [UKCustomer.Services@gilead.com](mailto:UKCustomer.Services@gilead.com)

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

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

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

**TO ALL CHEMISTS, DOCTORS ON THE LISTS**

Pharmaceutical Services  
2 Franklin Street  
BELFAST  
BT2 8DQ

Telephone No. 028 9536 0333

**12<sup>TH</sup> February 2021**

Pharmaceutical website: <http://www.hscbusiness.hscni.net>