



PRODUCT RECALL

Zerbaxa 1 g/0.5 g powder for concentrate for solution for infusion
Marketing Authorisation Number: EU/1/15/1032/001
All Batches

18th December 2020

Dear Wholesaler,

This is to inform you of a recall of all in-date batches of the above product.

This recall is going to hospital level.

This action has been agreed with the Health Products Regulatory Authority (HPRA).

The reason for the recall is due to the risk that the product may be non-sterile.

Please take the following actions:

1. Immediately identify and quarantine any units of this product which you have in your possession.
2. Please return the units to your supplier, indicating that they are being returned as a result of this recall action. The final date for recalled stock to be received back for credit is 31-Jan-2021.
3. If you have supplied units of this product to any other wholesaler which could still be in-date, please forward them a copy of this letter. The only batch on the market that remains in-date is Batch S041245; it was first distributed on May 1st 2020, so you will not need to search for supply records before this date.

This recall will result in this product being unavailable on the market for a period of time. We are endeavouring to make replacement stock available as soon as possible. We do not at this time have an expected date on which replacement stock will be available. Until further notice, this product will be unavailable.

We apologise for any inconvenience this action may cause. For questions about this recall please contact: Catherine Slevin at 01 297 0056 or Catherine.slevin@merck.com.

Sinead Tuite

Sinead Tuite
Associate Director
Digital & Commercial Operations