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MSD

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 Hospital Pharmacist,

This is to inform you of a voluntary global recall of all batches of the above product.

This recall is going to hospital level.

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

The reason for the recall is due to the risk that the product may be non-sterile. Out-of-specification sterility test results have been recently identified with seven batches placed on various markets. Five of those batches tested positive for the microorganism Ralstonia pickettii, while the other two batches produced turbid results during the sterility test, but in those samples the microorganism could not be identified.

R. pickettii is a strictly aerobic, oxidase positive, non-fermenting, non-motile, non-spore forming, Gram-negative rod. It is commonly found in soil and water. It is considered to be an opportunistic pathogen, particularly in those who are immunosuppressed or are in some other way debilitated.

The available evidence indicates that the presence of viable R. pickettii microorganisms in vials of Zerbaxa is sporadic and the likelihood that the vials on the market contain viable R. pickettii in sufficient quantities to cause serious adverse health consequences is low. However, a potential safety risk remains and this is greatest in high-risk patients – those who are immunocompromised and critically ill , as well as neonates. Based on the available information at this time, the probability of serious adverse health consequences in patients who have recently received Zerbaxa is considered extremely remote for the overall population, and remote in high-risk populations.

Please take the following actions:

1. Immediately identify and quarantine any units of this product which you have in your possession. This includes units within your pharmacy, on wards and at any other relevant locations within your hospital.

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 pharmacy or clinic outside your hospital which could still be in-date, please forward them a copy of this letter. The only batch on the

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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.

4. Please bring the above information to the attention of relevant healthcare professionals within your hospital, so that patients who have recently received units from this product may be monitored accordingly.

5. MSD recommends that healthcare professionals should immediately discontinue use of Zerbaxa in their patients and consider an alternative treatment plan. When culture and susceptibility information are available for individual patients, an appropriate antibacterial therapy should be selected. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Please note that, if any units are being infused at the time of receipt of this recall letter, there is no requirement to stop the infusion.

This recall will result in Zerbaxa being unavailable on the market for a period of time. We are endeavouring to make replacement stock of this product 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.

Please note that a Dear Healthcare Professional Letter (DHPC) about this issue will shortly be sent to hospital pharmacists, microbiologists and anaesthesiologists.

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

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