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MSD

December, 22nd 2020

Important Information about a recent Product Recall
Zerbaxa (ceftolozane / tazobactam) 1 g/0.5 g powder for concentrate for solution for infusion (all batches)
Marketing Authorisation Number: EU/1/15/1032/001

Ref: IE-ZER-00006

Dear Healthcare Professional,

MSD in agreement with the European Medicines Agency and the Health Products Regulatory Authority would like to inform you of the following:

Summary

- **All batches Zerbaxa 1 g/0.5 g powder for concentrate for solution for infusion were recalled in Ireland on December 18th 2020 as a result of a sterility assurance-related issue with the product. This recall was part of a global recall of the product by MSD.**
- **The product will be unavailable in Ireland (and elsewhere) for a period of time. We are endeavouring to make replacement stock available as soon as possible, but 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.**
- **Healthcare professionals are advised to immediately stop using Zerbaxa and consider an alternative treatment for their patients.**
- **The background to this recall is as follows:**
  - **Seven batches of Zerbaxa (ceftolozane/tazobactam) failed sterility testing during batch release testing performed by MSD. Five of those batches tested positive for the microorganism Ralstonia pickettii, while the other two batches produced turbid results that could not be identified. None of these seven batches were released to the market.**
  - **All product batches distributed to the market before this incident met their registered specifications for release, including for sterility. However, as a precautionary measure, MSD is recalling all Zerbaxa batches within expiry date.**
  - **This is a voluntary recall to Hospital Pharmacy level. A recall letter was issued by MSD to Hospital Pharmacies in Ireland on December 18th 2020.**

Background on the safety concern:

Zerbaxa (ceftolozane/tazobactam) is indicated for the treatment of the following infections in adults: complicated intra-abdominal infections, acute pyelonephritis, complicated urinary tract infections; hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP).

According to the analysis performed by MSD, seven batches of Zerbaxa failed sterility tests and manufacturing of the product has been temporarily stopped. Five of these batches tested positive for *Ralstonia pickettii* and two batches produced turbid results that could not be further identified. The investigation into the source of the contamination is ongoing and the seven batches have not been released to the market.

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While all product batches distributed to the market met the registered specifications for release, including for sterility, as a precautionary measure, we have initiated a recall to hospital level of all in-date Zerbaxa batches. Accordingly, MSD is hereby advising healthcare professionals (HCPs) to immediately discontinue use of Zerbaxa in their patients. HCPs should consider an alternative treatment.

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. *R. pickettii* is considered to be an opportunistic pathogen, particularly in patients who are immunocompromised or in critically ill patients, as well as neonates.

Regarding the batches of Zerbaxa that were released on the market, there was a potential safety risk as a result of the potential for the *R. pickettii* issue to cause adverse health consequences, particularly in high-risk patients (such as immunocompromised and critically ill patients). It should be noted that, at this stage, no safety signals in relation with this quality defect issue have been reported.

Call for reporting:

For questions about this issue or to report any adverse events, please contact Medical Information at medinfo_ireland@merck.com or at 01-2998700.

Please note that suspected adverse reactions should also be reported to the HPRA electronically via the website www.hpra.ie or by email at medsafety@hpra.ie.

We apologise for the impact of the unavailability of Zerbaxa. We are committed to doing our utmost to resume supply of the medicine for patients and prescribers around the world as quickly as possible.

Company contact point:

If you have any questions, please contact us at:

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Yours Sincerely

Ceara Belviso

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