



Merck Sharp & Dohme (UK) Limited  
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22<sup>nd</sup> December 2020

**GLOBAL RECALL: Zerbaxa (ceftolozane / tazobactam) 1 g/0.5 g powder for concentrate for solution for infusion**

Dear Healthcare Professional,

MSD in agreement with the European Medicines Agency and Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

***Summary***

- **Seven batches of Zerbaxa (ceftolozane/tazobactam) failed sterility tests. Five of these batches tested positive for *Ralstonia pickettii* according to the analysis performed by MSD. None of these batches have been released to the market.**

- **All product batches distributed to the market before this incident have met the registered specifications for release, including for sterility.**

**However, as a precautionary measure, MSD has decided to recall all Zerbaxa within expiry.**

- **Health care professionals should immediately stop using Zerbaxa and consider an alternative treatment for their patients.**

***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.

*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 currently released on the market, there is a potential

safety risk to cause adverse health consequences, particularly in high-risk patients (such as immunocompromised and critically ill patients). It should be noticed that at this stage no safety signals in relation with this quality defect have been reported. However, while all product batches distributed to the market has met the registered specifications for release, including for sterility, as a precautionary measure, a Class II (healthcare professional level) global recall of all Zerbaxa within expiry has been initiated.

Accordingly, MSD are hereby informing healthcare professionals (HCPs) to immediately discontinue use of Zerbaxa in their patients. HCPs should consider alternative treatment.

### ***Call for reporting***

For questions about this recall or to report any adverse events, please contact MSD Medical Information Phone number: 01992 467272.

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Please report any suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.

It is easiest and quickest to report ADRs online via the Yellow Card website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard), or search for MHRA Yellow Card in the Google Play or Apple App Store.

We recognise that ZERBAXA is an important choice for patient care and apologise for the impact of the unavailability of the product. We are committed to doing our utmost to resume supply of ZERBAXA for patients and prescribers around the world as quickly as possible.

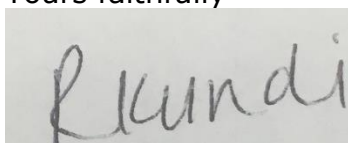
### ***Company contact point***

For stock control enquiries please contact [customerservice.msduk@msd.com](mailto:customerservice.msduk@msd.com)  
Phone number: 01992 452094

For more information or medical information at [medicalinformationuk@msd.com](mailto:medicalinformationuk@msd.com)

Phone number: 01992 467272

Yours faithfully



**Rina Kundi**  
**Director of Medical Affairs - Specialty Care**