



DRUG ALERT CLASS 2 MEDICINES RECALL

Action Within 48 Hours Pharmacy and Wholesaler Level Recall

Date: 16 December 2020 EL (20)A/60 Our Ref: MDR 060-12/20

Dear Healthcare Professional.

Merck Sharp & Dohme Limited

Zerbaxa 1g/0.5g Powder for Concentrate for Solution for EU/1/15/1032/001 Infusion

Batch Number	Expiry Date	Pack Size	First Distributed
S036625	31/12/2021	10 X 20ml	April 2020
S038424	31/12/2021	10 X 20ml	January 2020
S041245	31/12/2021	10 X 20ml	April 2020
T001191	31/12/2021	10 X 20ml	September 2020
T001192	31/12/2021	10 X 20ml	March 2020
T031915	30/04/2022	10 X 20ml	November 2020

Active Pharmaceutical Ingredient: ceftolozane sulfate / tazobactam sodium

Brief description of the problem

Merck Sharp & Dohme Limited is recalling the above batches due to the presence of *Ralstonia pickettii* in recent batches that were manufactured. The above batches are recalled as a precautionary measure whilst investigations into the microbiological quality of the distributed products are underway.

The potential for contamination of the above batches is low. If *R. pickettii* is found to be present, the risk that these products would contain viable *R. pickettii* in a level that could cause serious adverse health consequences is considered to be low.

R. pickettii is a gram-negative, non-motile, non-spore-forming, rod-shaped bacteria found in soils, rivers, and lakes. It is also present in biofilms bacteria (collective of one or more types of microorganisms that can grow on surfaces) in industrial plastic water systems.

Advice for healthcare professionals

Stop supplying the above batches immediately. Quarantine all stock and return it to your supplier using your supplier's approved process.

If patients experience a worsening of symptoms or other suspected side effects during therapy with Zerbaxa, these should be reported via the <u>Yellow Card scheme</u>.

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Further Information

For stock control enquiries please contact customerservice.msduk@msd.com Phone number: 01992 452094

For more information or medical information at medicalinformationuk@msd.com

Phone number: 01992 467272

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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