



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 31 January 2022

EL (22)A/03

Our Ref: MDR 046-01/22

Dear Healthcare Professional,

Antibiotice SA

Piperacillin/Tazobactam 4 g/0.5g Powder for solution for infusion PL 16329/0002

Batch No	Expiry Date	Pack Size	First Distributed
P3430007	10.2023	Box x 10 vials	Not distributed yet
P3430009	10.2024	Box x 10 vials	Not distributed yet
P3430010	10.2024	Box x 10 vials	Not distributed yet
P3430011	10.2024	Box x 10 vials	Not distributed yet
P3430012	10.2024	Box x 10 vials	Not distributed yet
P3430013	10.2024	Box x 10 vials	Not distributed yet
P3430014	10.2024	Box x 10 vials	Not distributed yet
P3430015	10.2024	Box x 10 vials	Not distributed yet

Active Pharmaceutical Ingredients: Piperacillin (as sodium salt) and Tazobactam (as sodium salt).

Brief description of the problem

Antibiotice SA have identified an error on PIL of the above batches regarding the sodium content. The correct content of sodium is presented in the following table:

Product	Marketing Authorization (MA)	Current PIL text (incorrect)	Required PIL text acc. to MA (correct)
Piperacillin / Tazobactam 4g/0.5 g, powder for solution for infusion	PL 16329/0002	Piperacillin/Tazobactam contains sodium Piperacillin/Tazobactam 4 g/0.5 g contains approximately 9.39 mmol (108 mg) of sodium	Piperacillin/Tazobactam contains sodium Piperacillin/Tazobactam 4 g/0.5 g contains approximately 9.39 mmol (216 mg) of sodium

The PIL have correct information for sodium content expressed in mmol (9.39 mmol), but wrong sodium content expressed in mg (108 mg, instead of 216 mg). The correct sodium content is also stated in the SPC (9.39 mmol, respectively 216 mg of sodium).



Advice for healthcare professionals

The impacted batches of Piperacillin/Tazobactam 4g/0.5 g, powder for solution for infusion product is within specification and there is no issue with product quality. The product is supplied as part of an NHS tender and the affected batches are not being recalled.

Since all batches are within specification and there are no quality issues with the product, the batches on hold awaiting distribution will be sold and have been included in this notification for information. The batches have been approved by the MHRA.

Healthcare professionals are advised to calculate the sodium content (for patients with sodium restricted diet) when administering this product using the value of 9.39 mmol (corresponding to 216 mg) of sodium for the product Piperacillin / Tazobactam 4 g/0.5 g powder for solution for infusion.

Antibiotice SA have confirmed that all future batches will contain the correct PIL in compliance with approved Marketing Authorisation.

Further Information

For medical information please contact:

medical@antibiotice.ro

For stock control queries please contact:

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

Yours faithfully

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