



# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION

**Caution in Use**  
**Distribute to Pharmacy / Wholesaler Level**

Date: 23 October 2023

EL(23)A/38

Our Ref: MDR 038-09/23

Dear Healthcare Professional,

### Sandoz Limited

**Zinacef 250mg powder for solution for injection or infusion vials**

**PL 48870/0039**

**SNOMED Code 4740211000001106**

Batch Number	Expiry Date	Pack Size	First Distributed
23K01810	11-2025	1	07/06/2023
23K00020	09-2025	1	30/03/2023
23K00021	09-2025	1	30/03/2023
2004E2	03-2025	1	31/10/2022
2003E2	05-2025	1	31/10/2022

**Zinacef 750mg powder for solution for injection or infusion vials**

**PL 48870/0040**

**SNOMED Code 3939311000001103**

Batch Number	Expiry Date	Pack Size	First Distributed
22K01918	08-2025	1	02/06/2023
22K01919	09-2025	1	02/06/2023
23K00019	09-2025	1	02/06/2023
22K00713	08-2025	1	22/12/2022
22K00604	08-2025	1	22/12/2022
2002E2	06-2025	1	07/10/2022

**Zinacef 1.5g powder for solution for injection or infusion vials**

**PL 48870/0041**

**SNOMED Code 4530311000001103**

Batch Number	Expiry Date	Pack Size	First Distributed
23K02206	04-2026	1	27/06/2023
2002E2.	04-2025	1	31/05/2023

Active Pharmaceutical Ingredient: Cefuroxime Sodium



## GlaxoSmithKline Ltd

**Zinacef 1.5g powder for solution for injection or infusion vials**

**PL 00004/0263**

**SNOMED Code 4530311000001103**

Batch Number	Expiry Date	Pack Size	First Distributed
2003E1	02-2024	1	13/04/2021
2005E1	02-2024	1	07/06/2021
2006E1	04-2024	1	06/07/2021
2007E1	04-2024	1	04/10/2021
2009E1	07-2024	1	04/10/2021
2010E1	07-2024	1	06/12/2021
2011E1	10-2024	1	06/12/2021
2013E1	10-2024	1	13/12/2021
2014E1	10-2024	1	07/02/2022

**Zinacef 250mg powder for solution for injection or infusion vials**

**PL 00004/0263**

**SNOMED Code 4740211000001106**

Batch Number	Expiry Date	Pack Size	First Distributed
2001E2	10-2024	1	29/01/2022
2005E1	09-2024	1	03/03/2022
2002E1	12-2023	1	05/03/2021
2004E1	07-2024	1	07/11/2021
2003E1	07-2024	1	11/11/2021

**Zinacef 750mg powder for solution for injection or infusion vials**

**PL 00004/0263**

**SNOMED Code 3939311000001103**

Batch Number	Expiry Date	Pack Size	First Distributed
2008E1	07-2024	1	07/11/2021
2001E2	12-2024	1	03/03/2022
2009E1	10-2024	1	03/03/2022
2005E1	05-2024	1	28/07/2021
2002E1	01-2024	1	02/04/2021
2003E1	03-2024	1	02/06/2021
2004E1	04-2024	1	17/06/2021
2006E1	07-2024	1	22/10/2021
2001E1	12-2023	1	10/02/2023

Active Pharmaceutical Ingredient: Cefuroxime Sodium



### Brief description of the problem

Sandoz, the Marketing Authorisation Holder (MAH), has detected that information on the diluents in the Patient Information Leaflet (PIL) and Summary of Product Characteristics (SmPC) of cefuroxime offer possibility for both intramuscular (IM) and intravenous (IV) administration. The PIL and SmPC state that cefuroxime sodium is compatible with aqueous solutions containing up to 1% lidocaine hydrochloride. However, dilution with lidocaine is intended only for intramuscular (IM) use. As this is not explicitly mentioned, the MAH considers this to pose a potential for medication errors.

The current instructions within the PIL and SmPC, and the corrected instructions (for future PILs and SmPCs) are detailed below:

Current instructions within PIL and SmPC	Corrected instructions [changes underlined]
<p>Instructions for reconstitution</p> <p>Compatibility 1.5 g cefuroxime sodium constituted with 15 mL Water for Injection may be added to metronidazole injection (500 mg/100 mL). 1.5 g cefuroxime sodium is compatible with azlocillin 1 g (in 15 mL) or 5 g (in 50 mL). Cefuroxime sodium (5 mg/mL) in 5% w/v or 10% w/v xylitol injection may be used. Cefuroxime sodium is compatible with aqueous solutions containing up to 1% lidocaine hydrochloride.</p>	<p>Instructions for reconstitution</p> <p>Compatibility 1.5 g cefuroxime sodium constituted with 15 mL Water for Injection may be added to metronidazole injection (500 mg/100 mL). 1.5 g cefuroxime sodium is compatible with azlocillin 1 g (in 15 mL) or 5 g (in 50 mL). Cefuroxime sodium (5 mg/mL) in 5% w/v or 10% w/v xylitol injection may be used <u>for intravenous use only</u>.</p> <p><u>Zinacef 250 mg, 750 and 1.5 g powder for solution for injection or infusion (intramuscular use only)</u> Cefuroxime sodium is compatible with aqueous solutions containing up to 1% lidocaine hydrochloride <u>for intramuscular use</u>.</p>

**The MAH would like to make clear that reconstitution with aqueous solutions containing up to 1% lidocaine hydrochloride is intended only for intramuscular (IM) use.**

Note: This problem impacts Zinacef batches marketed by the current Marketing Authorisation Holder, Sandoz Ltd, and the former Marketing Authorisation Holder GlaxoSmithKline Ltd.

### Advice for healthcare professionals

There is no risk to product quality because of this issue, therefore the affected batches are not being recalled. Healthcare professionals are advised to ensure they are aware that Zinacef products reconstituted with aqueous solutions containing up to 1% lidocaine hydrochloride are intended only for intramuscular (IM) use.

### Advice for patients

No further action is required by patients, the product is administered by healthcare professionals directly. If you have concerns about a medicine you may be using, please contact your healthcare professional.



Medicines & Healthcare products  
Regulatory Agency

Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA [Yellow Card scheme](#).

**Further Information**

For more information, medical information queries, please contact: [sandozgb@EU.propharmagroup.com](mailto:sandozgb@EU.propharmagroup.com),  
Telephone: +44 1276 698 101. For stock control queries, please contact: [sales.sandoz-gb@sandoz.com](mailto:sales.sandoz-gb@sandoz.com),  
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Yours faithfully

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