MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Distribute to Pharmacy/Wholesaler Level

Date: 23 May 2023 EL (23)A/19 Our Ref: MDR 043-03/23

Dear Healthcare Professional,

Drugsrus Limited / Dawa Limited

Metronidazole 200 mg/5 ml Oral Suspension

PL 30684/0236

SNOMED Code 34746011000001100

Batch Number	Expiry Date	Pack Size	First Distributed
C20070	03/2025	100 ml	11/10/2022
C20071	03/2025	100 ml	24/01/2023
C20072	03/2025	100 ml	28/12/2022

Active Pharmaceutical Ingredient: metronidazole benzoate

Brief description of the problem

Drugsrus Limited has informed the MHRA that a small number of bottles of Metronidazole 200 mg/5 ml Oral Suspension 100ml are leaking from the cap. The probable root cause for this defect is related to the possibility of a slight defect in the cap or bottle threads. Only the batches listed in this notification are affected. Due to the very low number of complaints received and the high visibility of the defect usually prior to dispensing, the product is not currently being recalled.

Advice for healthcare professionals

Healthcare professionals are advised to check any incoming bottles from the batches listed above for leaks from the cap.

Do not dispense any bottles that are found to be leaking. Quarantine any affected bottles immediately. Contact Drugsrus Limited (see Further Information section) for replacement and further advice.

Advice for patients

If you have received a bottle of Metronidazole 200 mg/5 ml Oral Suspension 100ml that is leaking, contact your pharmacy team to arrange a replacement. Please return the leaking bottle to the pharmacy – they will provide you with another bottle so you can complete your course of treatment.

If you have concerns about a medicine you may be using, please contact your healthcare professional.

Patients who experience adverse reactions or have any questions about their medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA <u>Yellow Card</u> scheme.

Further Information

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For more information, medical or supply enquiries, please contact Drugsrus Limited on 020 8423 3800, or email info@drugsrus.co.uk.

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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