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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

12 August 2024

Dear Healthcare Professional,

**DRUG ALERT CLASS 4 DRUG ALERT 36 2024 – CLASS 4 MEDICINES DEFECT
INFORMATION – CAUTION IN USE – STAR PHARMACEUTICALS LTD – DIFLUCAN
ORAL SUSPENSION 40MG/ML**

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team





MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level

Date: 12 August 2024

EL (24)A/36

Our Ref: DMRC-31353215

Dear Healthcare Professional,

Star Pharmaceuticals Limited

Diflucan Oral Suspension 40mg/ml

PLPI 20636/3070

SNOMED Code: N/A

Batch No	Expiry Date	Pack Size	First Distributed
B861104	09/2026	35 ml	20/05/2024
B694104	12/2024	35 ml	11/06/2024

Active Pharmaceutical Ingredient: fluconazole

Brief description of the problem

Star Pharmaceuticals Limited has informed the MHRA that an error has been identified in the Patient Information Leaflet (PIL) for two batches of Diflucan Oral Suspension 40mg/ml.

Section 6 of the PIL states “**50mg** of fluconazole per 5ml” instead of “**200mg** of fluconazole per 5ml”. The other sections of the PIL and product information state the correct strength of 200mg of fluconazole per 5ml.

Advice for healthcare professionals

There is no risk to product quality because of this issue, therefore the affected batch is not being recalled. Healthcare professionals should continue to use the product as normal but be aware of the typographical error highlighted in this notification. Star Pharmaceuticals Limited have also confirmed that they have identified all customers who have been supplied with this product and will initiate direct contact with the relevant customers.

Advice for patients

No further action is required by patients. If you have received or receive the impacted batches of Diflucan Oral Suspension 40mg/ml listed in this notification, please continue to take your medicine as prescribed by your doctor and as per the dispensing label. 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 the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Further Information

For medical information enquiries please contact the distributor, Drugsrus Limited on 0208 423 3800, info@drugsrus.co.uk.



Medicines & Healthcare products Regulatory Agency

For stock control enquiries please contact the distributor, Drugsrus Limited on 0208 423 3800, 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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