Medicines & Healthcare products Regulatory Agency

# MEDICINES NOTIFICATION

**CLASS 4 MEDICINES DEFECT INFORMATION**

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

Date: 22 February 2023 EL (23)A/04 Our Ref: MDR 133-02/23

Dear Healthcare Professional,

## Reckitt Benckiser Healthcare (UK) Limited

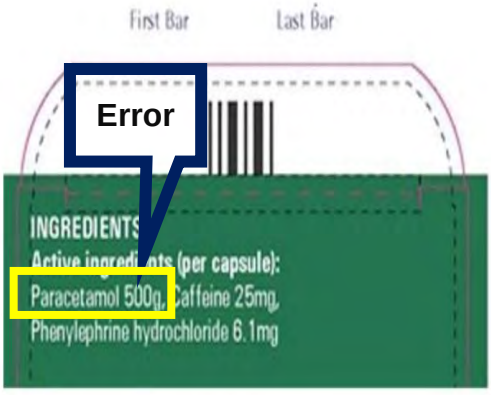
## Lemsip Max Cold and Flu Capsules PL 00063/0104

| Batch Number | Expiry Date | Pack Size | First distributed |
|---|---|---|---|
| AED954 | 1 DEC 25 | 16 capsules | 24 Jan 2023 |
| AED955 | 1 DEC 25 | 16 capsules | 17 Jan 2023 |
| AED956 | 1 DEC 25 | 16 capsules | 25 Jan 2023 |
| AED957 | 1 JAN 26 | 16 capsules | 17 Jan 2023 |
| AED958 | 1 JAN 26 | 16 capsules | 30 Jan 2023 |
| AED960 | 1 JAN 26 | 16 capsules | 06 Feb 2023 |
| AED961 | 1 JAN 26 | 16 capsules | 06 Feb 2023 |
| AED981 | 1 OCT 25 | 8 capsules | 04 Jan 2023 |
| AEE003 | 1 JAN 26 | 8 capsules | 06 Feb 2023 |

**Active Pharmaceutical Ingredients:** Paracetamol, caffeine and phenylephrine hydrochloride

**Brief description of the problem**
Reckitt Benckiser Healthcare (UK) Limited has informed the MHRA that a typographical error has been identified on the end flap of the outer carton of the above batches of Lemsip Max Cold & Flu Capsules. The content of paracetamol per capsule was stated as 500**g** (grams) instead of 500**mg** (milligrams). The paracetamol content of each capsule is correctly stated in Patient Information Leaflet (PIL).





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**Advice for healthcare professionals**
Healthcare professionals should note that there is no risk to product quality and/or efficacy, therefore the affected batches are not being recalled.

Where queries are received regarding the discrepancy with the paracetamol content on the outer carton, healthcare professionals and retailers should signpost patients to Section 6 of the PIL, which states the correct content of paracetamol as 500**mg** (milligrams).

| Section 6 of the PIL |
| --- |
| Contents of the pack and other information |
| What this medicine contains: |
| • The active ingredients are: paracetamol 500mg, caffeine 25mg and phenylephrine hydrochloride 6.1mg |

Patients should also be reminded to follow the dosing instructions on the outer carton and/or Section 3 of the PIL to ensure that the recommended dose is not exceeded.

**Advice for patients**
This notification relates to a typographical error on end flap of the outer packaging of the affected batches of this medicine. The text on the outer pack says 500**g** (grams) instead of 500**mg** (milligrams) of paracetamol.

Patients do not need to take any action as the medicine itself is not affected, and the dosing instructions on the outer carton are correct. The company has confirmed that the content of paracetamol in each capsule within the packet is correct, and that the content of paracetamol is also correctly reflected in the Patient Information Leaflet that is packaged inside the packet.

Patients should always read the leaflet that accompanies their medicines and ask a healthcare professional if they are unsure how many capsules of the medicine they should take.

Any suspected adverse reactions should be reported via the MHRA Yellow Card scheme.

**Further Information**

For medical information and stock control queries please contact: ConsumerHealth_GB@Reckitt.com and / or 03332005345.

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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