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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

22 February 2023

Dear Healthcare Professional

**DRUG ALERT - EL (23)A/04 - Caution in Use - Class 4 Medicines Defect Information:
Reckitt Benckiser Healthcare (UK) Limited, Lemsip Max Cold and Flu Capsules,**

Please see the attached 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 forward this alert 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

Grace Jamieson
Medicines Policy Team



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 500g (grams) instead of 500mg (milligrams). The paracetamol content of each capsule is correctly stated in Patient Information Leaflet (PIL).





Medicines & Healthcare products Regulatory Agency

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 500mg (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 500g (grams) instead of 500mg (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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