



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

**Action Within 48 Hours
Retail/Wholesaler Level Recall**

Date: 11 November 2021

EL (21)A/28

Our Ref: MDR 055-11/21

Dear Healthcare Professional,

Wrafton Laboratories Limited (trading as Perrigo)

Active Pharmaceutical Ingredients: Paracetamol 300 mg, Caffeine 25 mg and Phenylephrine hydrochloride 5 mg

Brief description of the problem

Perrigo are recalling the above batches of Cold & Flu Relief Capsules (GSL) – Various Liveries, due to an error on the leaflet and carton for the products as noted above. The leaflet and carton incorrectly states that for Adults, the elderly and children 12 years and over, the dose should be 2 capsules every 4 to 6 hours as required, up to a maximum of 12 capsules in any 24 hour period. The leaflet and carton dosage instructions are those which were in use prior to the paediatric paracetamol posology update implemented by the MHRA.

As each capsule contains 300mg of paracetamol, 12 capsules would equate to 3.6g/day. This exceeds the MHRA recommended maximum dose for 12-15 year old's, which is 3g/day.

The correct posology instructions should state the following:

- **Adults and children 16 years and over: 2 capsules every 4 to 6 hours as required, up to a maximum of 12 capsules (6 doses) in any 24 hour period.**
- **Children aged 12 to 15 years: 2 capsules every 4 to 6 hours as required, up to a maximum of 8 capsules (4 doses) in any 24 hour period.**

This product is only sold from various retail stores directly and impacts all products that share the PL number, but packaged in different liveries. If you have any concerns, please contact Perrigo using the details below.

This recall is not directed to patient level due to the safety assessment on the short-term use of this product by children aged 12 to 15 years.

Advice for patients and consumers

- Please refer to the correct dosage instructions listed above for Children aged 12 to 15 years.
- If you experience any side-effects, or have any questions or concerns about your health, speak to your doctor or pharmacist.
- Report any suspected side effects via the [Yellow Card Scheme](#)



Advice for retailers and wholesalers

- Stop supplying the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Advice for healthcare professionals

- Stop supplying the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.
- Any suspected side effects should be reported via the [Yellow Card Scheme](#)

Further Information

For more information, please contact: Perrigo Customer Services Team on 0203 598 9603 or UKLOCustomerService@perrigo.com

For stock control queries, please contact: Perrigo Service Team on 01226 704711 or customerservice@perrigouk.com

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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