



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Patient/Retail/Wholesaler Level Recall

Date: 12 October 2021

EL (21)A/24

Our Ref: MDR 098-10/21

Dear Healthcare Professional,

Wrafton Laboratoires Limited (trading as Perrigo)

Tesco Flu-Max All In One Chesty Cough & Cold Powder for Oral Solution (GSL)

PL 12063/0104

Batch Number	Expiry Date	Pack Size	First Distributed
9MW0145	Nov 2022	10s	16 Mar 2020
0CW0054	Jan 2023	10s	07 Apr 2020
0FW0133	May 2023	10s	12 May 2021

Active Pharmaceutical Ingredients: Paracetamol 1000 mg/sachet; Guaifenesin 200 mg/sachet;
Phenylephrine hydrochloride 12.2 mg/sachet

Brief description of the problem

Perrigo are recalling the above batches due to an error on the sachet contained within the outer carton. The sachet artwork incorrectly states that children aged 12 years and over can take 4 sachets containing 1000mg of paracetamol (i.e. 4 doses over a 24 hour period), whereas the carton, PIL and SmPC state that the product is not to be given to the under 16s. The sachets dosage instructions are those which were in use prior to the paediatric paracetamol posology update implemented by the MHRA.

The correct posology instruction on the outer carton, patient information leaflet (PIL) and summary of product characteristics (SmPC) comply with regulatory requirements but differ from that on the product sachet which is incorrect. [See link to PIL containing the correct information](#)

This product should not be given to under 16s and therefore the product is being recalled from patients directly.

This product is only sold from Tesco stores directly and does not impact any other products that share the PL number, but packaged in different liveries. If you have any concerns, please contact Perrigo using the details below.

Advice for patients and consumers

- Stop using the product immediately and return this to Tesco Stores.
- 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

- Advise patients who have been supplied this product to stop using the product immediately and return this to Tesco Stores, where appropriate.
- 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

**Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574**