

## DRUG ALERT

### CLASS 2 MEDICINES RECALL

Action within 48 Hours

Retail / Wholesaler Level Recall

Dear Healthcare Professional

#### **Wrafton Laboratories Limited (trading as Perrigo)**

Cold & Flu Relief Capsules (GSL) – Various Liveries

PL 12063/0003

**Wilko Non-Drowsy Decongestant with Paracetamol PL 12063/0003**

Batch Number	Expiry Date	Pack Size (Capsules)	First Distributed
9CW0032	Dec-21	16	23/04/2019
9DW0077	Jan-21	16	10/09/2019
9GW0048	Apr-22	16	14/10/2019
9LW0165	Sep-22	16	21/02/2020
0DW0072	Jan-23	16	24/04/2020
0EW0108	Feb-23	16	09/10/2020
0FW0086	Apr-23	16	07/10/2021

#### **Spar Cold Relief Capsules**

PL 12063/0003

Batch Number	Expiry Date	Pack Size (Capsules)	First Distributed
9CW0030	Dec-21	16	22/03/2019
9EW0009	Jan-22	16	30/09/2019
9MW0018	Aug-22	16	17/03/2020
0AW0013	Aug-22	16	30/01/2020
0DW0071	Jan-23	16	22/04/2020
0FW0081	Apr-23	16	17/05/2021

**Essential Waitrose Cold & Flu Relief Capsules**

**PL 12063/0003**

Batch Number	Expiry Date	Pack Size (Capsules)	First Distributed
9KW0128	Aug-22	16	23/12/2019
0DW0092	Feb-23	16	05/05/2020
0GW0144	May-23	16	21/07/2020

**Aldi Health Essentials Cold Relief Capsules**

**PL 12063/0003**

Batch Number	Expiry Date	Pack Size (Capsules)	First Distributed
9FW0041	Mar-22	16	02/07/2019
9GW0049	Apr-22	16	27/08/2019
9HW0149	May-22	16	04/10/2019
0CW0186	Jan-23	16	17/09/2020
0GW0121	May-23	16	21/09/2020
0JW0055	May-23	16	14/10/2020

**ASDA Cold Relief Capsules**

**PL 12063/0003**

Batch Number	Expiry Date	Pack Size (Capsules)	First Distributed
9FW0065	Apr-22	16	17/07/2019
9GW0051	May-22	16	24/09/2019
9JW0005	Jul-22	16	19/11/2019
0AW0027	Sep-22	16	29/01/2020
0BW0098	Nov-22	16	03/03/2020
0CW0139	Nov-22	16	31/03/2020
0DW0093	Feb-23	16	24/09/2020
0FW0083	Apr-23	16	15/02/2021
0KW0008	Jul-23	16	01/10/2021

Batch Number	Expiry Date	Pack Size (Capsules)	First Distributed
9CW0031	Dec-21	16	24/04/2019
9EW0069	Mar-22	16	01/08/2019
9HW0087	Jun-22	16	26/11/2019
0AW0111	Nov-22	16	23/03/2020
0CW0184	Jan-23	16	11/08/2020
0EW0109	Feb-23	16	04/09/2020

**Superdrug Non-Drowsy Decongestant with Paracetamol**  
PL 12063/0003

Batch Number	Expiry Date	Pack Size (Capsules)	First Distributed
9EW0112	Mar-22	16	01/08/2019
0AW0016	Sep-22	16	23/03/2020
0DW0073	Jan-23	16	11/08/2020

**Sainsbury's Healthcare Cold Relief Capsules** PL 12063/0003

Batch Number	Expiry Date	Pack Size (Capsules)	First Distributed
9DW0138	Jan-22	16	21/08/2019
9JW0006	Jul-22	16	24/10/2019
9KW0126	Aug-22	16	20/12/2019
0BW0096	Nov-22	16	05/03/2020
0DW0117	Feb-23	16	12/05/2020
1AW0059	Aug-23	16	28/05/2021

**Sainsbury's Healthcare Sinus Dual Relief Capsules** PL 12063/0003

Batch Number	Expiry Date	Pack Size (Capsules)	First Distributed
9DW0075	Dec-21	16	17/05/2019
9HW0014	May-22	16	03/10/2019
9KW0127	Aug-22	16	03/02/2020
0AW0150	Sep-22	16	19/05/2020
0FW0084	Apr-23	16	15/12/2020
1DW0053	Feb-24	16	08/06/2021

**Lloyds Cold Relief Capsules**

**PL 12063/0003**

Batch Number	Expiry Date	Pack Size (Capsules)	First Distributed
9GW0050	Mar-22	16	09/09/2019
9MW0015	Aug-22	16	02/04/2020
0GW0143	May-23	16	16/09/2021

**WM Morrison Cold Relief Capsules**

**PL 12063/0003**

Batch Number	Expiry Date	Pack Size (Capsules)	First Distributed
9DW0076	Jan-22	16	23/09/2019
9HW0150	Jul-22	16	23/11/2019
0AW0151	Nov-22	16	24/02/2020
0EW0107	Feb-23	16	24/09/2020
0KW0007	Jul-23	16	18/08/2021
1JW0030	Jul-24	16	27/10/2021

**Boots Cold & Flu Relief Capsules**

**PL 12063/0003**

Batch Number	Expiry Date	Pack Size (Capsules)	First Distributed
9EW0113	Mar-22	16	03/09/2019
9FW0040	Mar-22	16	24/09/2019
9HW0026	Jun-22	16	07/10/2019
9HW0152	Jul-22	16	12/12/2019
9MW0017	Aug-22	16	07/03/2020
0AW0152	Nov-22	16	07/03/2020
0CW0183	Jan-23	16	22/09/2020
0DW0094	Feb-23	16	16/09/2021
0FW0087R	Apr-23	16	24/09/2021

**Boots Blocked Nose & Headache Relief Capsules**

**PL 12063/0003**

Batch Number	Expiry Date	Pack Size (Capsules)	First Distributed
9FW0039	Mar-22	16	17/09/2019

9HW0027	Jun-22	16	07/10/2019
9KW0125	Aug-22	16	20/12/2019
0AW0015	Sep-22	16	13/03/2020
0CW0185	Jan-23	16	22/09/2020
0DW0091	Feb-23	16	20/10/2020
1JW0022	Feb-24	16	04/10/2021

**Tesco Cold Relief Capsules**

**PL 12063/0003**

Batch Number	Expiry Date	Pack Size (Capsules)	First Distributed
9BW0110	Dec-21	16	02/04/2019
9EW0021	Jan-22	16	17/07/2019
9HW0011	May-22	16	01/11/2019
9KW0123	Jul-22	16	19/12/2019
9MW0016	Aug-22	16	03/02/2020
0AW0014	Sep-22	16	27/02/2020
0BW0097	Nov-22	16	07/03/2020
0CW0141	Jan-23	16	06/04/2020
0DW0090	Jan-23	16	10/09/2020
0FW0088	Feb-23	16	05/05/2021
0KW0006	Jul-23	16	28/07/2021

**Galpharm Cold Relief Capsules**

**PL 12063/0003**

Batch Number	Expiry Date	Pack Size (Capsules)	First Distributed
9FW0064	Apr-22	16	03/09/2019
9HW0025	Jun-22	16	25/10/2019
9HW0151	Jun-22	16	13/11/2019
9KW0124	Jul-22	16	19/12/2019
9LW0164	Aug-22	16	03/02/2020
0AW0153	Nov-22	16	19/03/2020
0CW0140	Jan-23	16	06/04/2020
0DW0116	Feb-23	16	19/06/2020

0FW0085	Apr-23	16	14/10/2020
0GW0066	Apr-23	16	26/03/2021
0KW0066	Aug-23	16	02/09/2021

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](mailto:UKLOCustomerService@perrigo.com)

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

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice.

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

**TO ALL CHEMISTS, DOCTORS ON THE LISTS**

Pharmaceutical Services  
2 Franklin Street  
BELFAST  
BT2 8DQ

Telephone No. 028 9536 0333

**11<sup>th</sup> November 2021**

Pharmaceutical website: <http://www.hscbusiness.hscni.net>