

## **MEDICINES RECALL**

# CLASS 2 MEDICINES RECALL, EL(25)A/35 Action within 48 hours

Issued 24 July 2025

## Distribute to Pharmacy/Wholesaler Level

#### **MARKETING AUTHORISATION HOLDER (MAH)**

CD Pharma Ltd

#### **MEDICINE DETAILS**

Flutiform 250 micrograms / 10 micrograms per actuation pressurised inhalation, suspension

PL: 20492/0724

Active Ingredient: fluticasone propionate/formoterol fumarate

30 Jun 2026

SNOMED code: n/a GTIN: **05060011835409** 

269881-24064FA-

30425

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
270185-24062FA- 30424	30 Jun 2026	120 Actuations	30 Jun 2025
270186-24065FA- 30443	30 Jun 2026	120 Actuations	04 Jul 2025
270774-24082FB- 30444	31 Jul 2026	120 Actuations	04 Jul 2025

120 Actuations

04 Jul 2025

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### **Background**

CD Pharma Ltd have notified the MHRA of an error on the outer carton of the product for the batches listed in this notification. While the total active content statement is correct, the delivered dose content statement is incorrect.

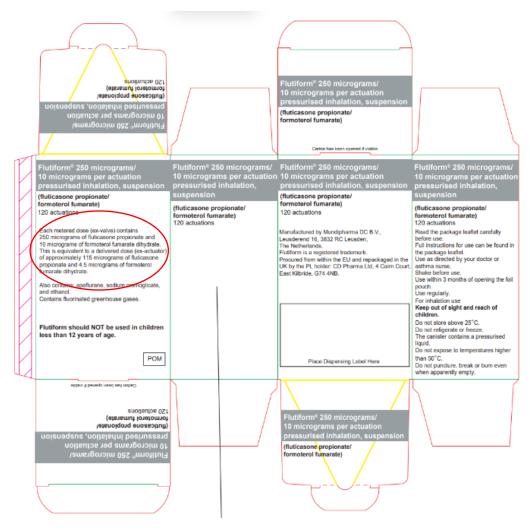
#### Incorrect active content statement

'Each metered dose (ex-valve) contains 250 micrograms of fluticasone propionate and 10 micrograms of formoterol fumarate dihydrate. This is equivalent to a delivered dose (ex-actuator) of approximately 115 micrograms of fluticasone propionate and 4.5 micrograms of formoterol fumarate dihydrate.'

#### **Correct active content statement**

'Each metered dose (ex-valve) contains 250 micrograms of fluticasone propionate and 10 micrograms of formoterol fumarate dihydrate. This is equivalent to a delivered dose (ex-actuator) of approximately 230 micrograms of fluticasone propionate and 9 micrograms of formoterol fumarate dihydrate.'

The other product details on the carton, including the name, strength and pharmaceutical form of the medicine are correct. The quality of the medicine is not impacted by the labelling defect.



#### **Advice for Healthcare Professionals:**

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

#### **Advice for Healthcare Professionals to Provide to Patients:**

Patients who are taking Flutiform 250 micrograms / 10 micrograms per actuation pressurised inhalation, suspension should continue to take the medication as prescribed by their healthcare professional. This issue only impacts the statement related to the delivered dose and the other product details on the carton, including the name, strength and pharmaceutical form of the medicine are correct.

This is a wholesale and pharmacy level recall that will be actioned by a healthcare professional. There is no quality issue with the product and patients can continue to take their medicine as prescribed.

Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

#### Additional information:

For all further enquiries please contact 01355 204 448 or email regaffairs@teleta.co.uk

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

#### Yours faithfully

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