



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

SNOMED code: n/a

GTIN: **05060011835409**

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
269881-24064FA-30425	30 Jun 2026	120 Actuations	04 Jul 2025

Incorrect active content statement	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 115 micrograms of fluticasone propionate and 4.5 micrograms of formoterol fumarate dihydrate.’	‘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 diagram illustrates the layout of a Flutiform inhaler box. The box is divided into several sections with different backgrounds (grey, white, green). The text is arranged as follows:

- Top Left (Grey background):** Flutiform® 250 micrograms/ 10 micrograms per actuation pressurised inhalation, suspension (fluticasone propionate/ formoterol fumarate) 120 actuations.
- Top Right (White background):** Flutiform® 250 micrograms/ 10 micrograms per actuation pressurised inhalation, suspension (fluticasone propionate/ formoterol fumarate). Below this, in a green box: Carton has been opened if visible.
- Middle Left (White background):** Flutiform® 250 micrograms/ 10 micrograms per actuation pressurised inhalation, suspension (fluticasone propionate/ formoterol fumarate) 120 actuations. Below this, a red circle highlights the text: 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. Below this, in a green box: Also contains: co-surfurane, sodium stearoylglucate, and ethanol. Contains fluorinated greenhouse gases.
- Middle Right (White background):** Flutiform® 250 micrograms/ 10 micrograms per actuation pressurised inhalation, suspension (fluticasone propionate/ formoterol fumarate) 120 actuations. Below this, in a green box: Manufactured by Mundipharma DC B.V., Leusderend 16, 3832 RC Leusden, The Netherlands. Flutiform is a registered trademark. Procured from within the EU and repackaged in the UK by the Pl. holder: CD Pharma Ltd, 4 Cairn Court, East Kilbride, G74 4NB.
- Bottom Left (White background):** Flutiform® 250 micrograms/ 10 micrograms per actuation pressurised inhalation, suspension (fluticasone propionate/ formoterol fumarate) 120 actuations. Below this, in a green box: Flutiform should NOT be used in children less than 12 years of age. Below this, in a white box: POM.
- Bottom Right (White background):** Flutiform® 250 micrograms/ 10 micrograms per actuation pressurised inhalation, suspension (fluticasone propionate/ formoterol fumarate) 120 actuations. Below this, in a green box: Read the package leaflet carefully before use. Full instructions for use can be found in the package leaflet. Use as directed by your doctor or asthma nurse. Shake before use. Use within 3 months of opening the foil pouch. Use regularly. For inhalation use. Keep out of sight and reach of children. Do not store above 25°C. Do not refrigerate or freeze. The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not puncture, break or burn even when apparently empty.

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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