Medicines & Healthcare products Regulatory Agency

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(25)A/12

Caution In Use

Issued 31 March 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Cross Healthcare Limited

MEDICINE DETAILS

Sirdupla 25 microgram/250 microgram per metered dose pressurised inhalation, suspension

PLPI: 20504/0109

Active Ingredient: salmeterol xinafoate/fluticasone propionate

SNOMED code: N/A

GTIN: 05056269902307

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
77518	12/2025	120 dose	06/01/2025

Background

Cross Healthcare Limited have informed the MHRA that there is a printing defect on the outer labels for the Sirdupla 25 microgram/250 microgram per metered dose pressurised inhalation, suspension, batch 77518.

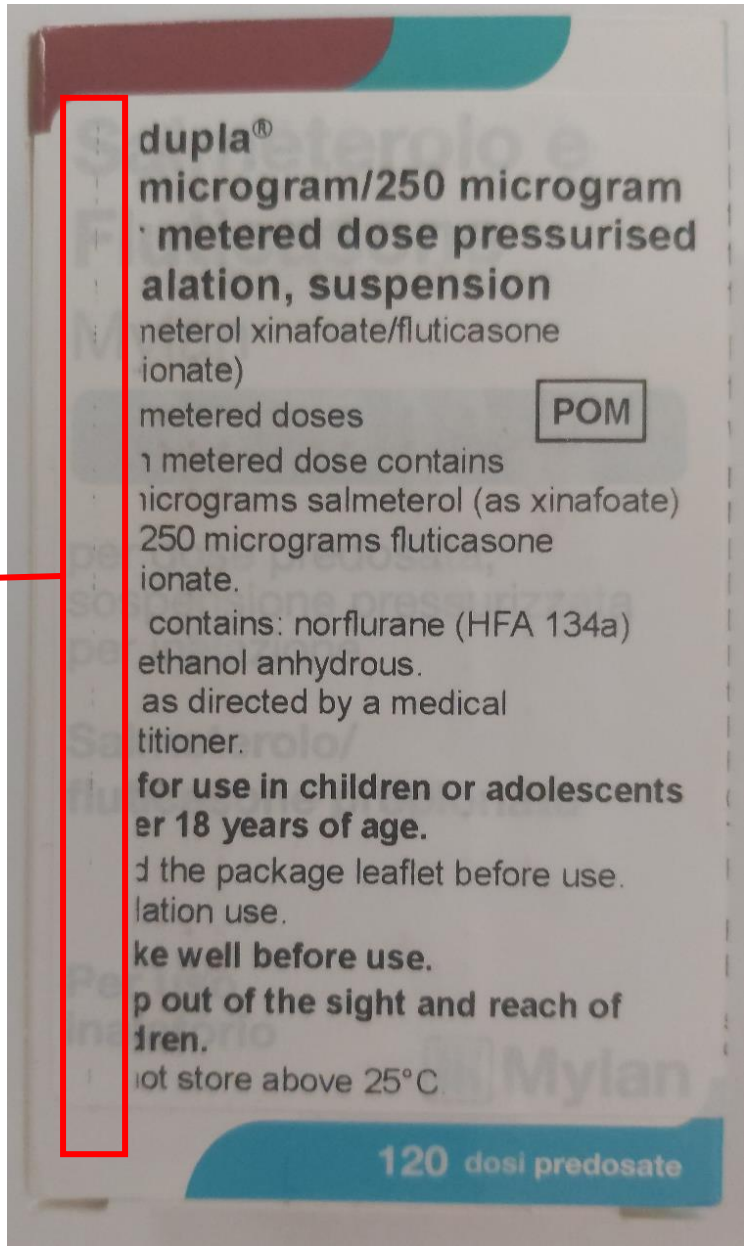
There is 5mm of missing text on the left-hand side of the outer label, please refer to the image in this notification for more information.

The defect is restricted to the outer label on the front face of carton, which is applied onto the carton by Cross Healthcare Limited following importation.

The product is as specified, Sirdupla 25 microgram/250 microgram per metered dose pressurised inhalation, suspension.

All other labels and the Patient Information Leaflet specify the correct information for Sirdupla 25 microgram/250 microgram per metered dose pressurised inhalation, suspension. The labelling defect has no impact on the medicinal product which can continue to be distributed, prescribed, dispensed and used.

The red box highlights where the information is missing from the outer label



Advice for Healthcare Professionals:

Healthcare Professionals are advised that if a unit is identified with this printing defect:

- The quality and efficacy of the medicinal product is not impacted by this defect and can continue to be prescribed, dispensed and used, as appropriate.
- The printing defect is restricted to the outer label shown in the image in this notification, all other labels and Patient Information Leaflet contain no printing defects and are compliant to PLPI 20504/0109.
- Reassure any concerned patients that this is a labelling defect only and that the product is Sirdupla 25 microgram/250 microgram per metered dose pressurised inhalation, suspension. Where necessary show them other labels or the Patient Information Leaflet that do not contain this error.

Advice for Healthcare Professionals to Provide to Patients:

Patients should continue to take medicines from the impacted units of batch 77518 as prescribed by your healthcare professional as the defect is restricted to the specific defect shown on the image in this notification.

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 further information please email gary@crosshealthcare.co.uk or telephone 01786 817707.

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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