Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 hours Pharmacy/Wholesaler Level Recall

Date: 09 December 2024

EL (24)A/62

Our Ref: DMRC-34091841

Dear Healthcare Professional,

Wockhardt UK Limited

WockAIR 160 microgram/4.5 microgram, inhalation powder PL 29831/0736

SNOMED Code 40106011000001102

Batch No	Expiry Date	Pack Size	First Distributed
NV6057	30 April 2026	2 pack inhaler	01 October 2024

Active Pharmaceutical Ingredient: budesonide/formoterol fumarate dihydrate

Brief description of the problem

Wockhardt UK Limited is recalling the above batch as a precautionary measure following the identification of a low number of units which may have a defect in the 'top case' resulting in a dose not being able to be dispensed.

Advice for healthcare professionals

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

Advice for patients

Wockhardt has advised MHRA that this is a rare defect and the pharmacy and wholesaler level recall is being undertaken as a precautionary measure. Patients should continue to take medicines from this batch as prescribed by your healthcare professional.

Patients should be aware that whilst a defect has been identified, it does not affect all inhalers within this batch. If a patient were to receive an inhaler with a defect, the defect would be obvious from the first attempted use of the product as the inhaler would not provide a dose.

Patients using an inhaler from this batch should continue to use the inhaler as the defect would not impact a working device. Patients that have an unopened inhaler from the batch in the table are advised to test the inhaler is working before their current inhaler runs out.

The batch number can be found at the bottom of the label on the back of the device. If patients find that their inhaler is affected by this defect, they should return it to their pharmacist who can advise on the provision of an alternative inhaler.

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 <u>MHRA Yellow Card</u> <u>scheme</u>.

Further Information

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For medical information enquiries please telephone 01978 661261 and ask for 'drug safety', or email <u>drug.safety@wockhardt.co.uk</u>.

For stock control enquiries please telephone 01978 661261 and ask for 'customer services', or email <u>group_uk_csu@wockhardt.co.uk</u>.

Recipients of this Medicines Recall 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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