Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

For Action: Assistant Director Integrated Care, Head of Pharmacy and Medicines Management, Strategic Planning and Performance Group & BSO
Heads of Pharmacy and Medicines Management of HSC Trusts
Regulation Quality Improvement Authority

From: Chief Pharmaceutical Officer
Professor Cathy Harrison
Castle Buildings
Upper Newtownards Road
Belfast BT4 3SQ

Telephone: 028 90 523219
Facsimile: 028 90 522335

E-Mail: cathy.harrison@health-ni.gov.uk

Our Ref: PHC/24/2024
Date: 18 June 2024

M E D I C I N E S N O T I F I C A T I O N

CLASS 3 MEDICINES RECALL

Action within 5 days

Pharmacy/Wholesaler Level Recall

Dear Healthcare Professional,

Teva UK Limited

PLGB 00289/2501

GoResp Digihaler

SNOMED Code: 42007211000001108

Batch No	Expiry Date	Pack Size	First Distributed
AGD11A	04/2026	160/4.5mcg (180 dose)	18/07/2023

GoResp Digihaler **PLGB 00289/2502**

SNOMED Code: 42007511000001106

Batch No	Expiry Date	Pack Size	First Distributed
AGD12A	04/2026	320/9mcg (90 dose)	18/07/2023

Active Pharmaceutical Ingredient: Budesonide/Formoterol Fumarate Dihydrate

Brief description of the problem

Teva UK Limited has informed the MHRA that it plans to withdraw from further sale all batches of GoResp Digihaler (budesonide and formoterol fumarate dihydrate) and the linked Digihaler App for commercial reasons. The inhalers containing the medicinal product are being withdrawn from the market because the App is no longer being supported, there is no product quality issue with the medicine itself.

From 1 June 2024 the Digihaler App described in the Patient Information Leaflet is no longer available for download from the Apple App Store and Google Play store. This means users will not be able to download the app, sign up, log in or load any new data.

This affects a very small number of patients who are currently using the App. However, the notification is being sent wider to ensure awareness and recall remaining stock.

Advice for healthcare professionals

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

If you are aware of patients using this inhaler, advise them that they should speak to their prescriber or a healthcare professional about their ongoing care. The patient can continue to use the inhaler, and the inhaler itself has a dose counter that is independent of the App, however the patient should be made aware that the App is no longer supported should it cease to function.

Advice for patients

No action is required by patients as this is a pharmacy and wholesaler level recall.

GoResp Digihaler does not need to be connected to the App in order for you to take your medicine. The electronic module does not control or interfere with the delivery of the medication through the inhaler.

Data from the App will be retained for 10 years and can be made available to individual users of the App on request.

If you are currently using this product, please contact your prescriber or another healthcare professional about your ongoing care. The dose indicator on the inhaler is independent of the App and will still function without the App.

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.

Further Information

For medical information, please contact medinfo@tevauk.com (Tel. 02075 407117) and stock control enquiries please contact customer.services@tevauk.com (Tel. 0800 590502).

Recipients of this Medicines Recall 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.

Yours sincerely

Professor Cathy Harrison
Chief Pharmaceutical Officer