Medicines & Healthcare products Regulatory Agency

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(25)A/26

Caution In Use

Issued 10 June 2025

Distribute to Pharmacy/Wholesaler and Retailer Level

MARKETING AUTHORISATION HOLDER (MAH)

Opella Healthcare UK LTD

MEDICINE DETAILS

Dulcolax Adult 5 mg Gastro-resistant Tablets

PL 53886/0025

Active Ingredient: bisacodyl

EAN: 5000283661894

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
240908	31/05/2027	20	25/04/2025
240909	31/05/2027	20	24/04/2025
241873	30/11/2027	20	07/05/2025
241875	30/11/2027	20	Not yet distributed
250222	31/12/2027	20	Not yet distributed
250307	31/01/2028	20	Not yet distributed
250308	31/01/2028	20	Not yet distributed

Background

Opella Healthcare UK LTD has informed the MHRA that there is an error on the artwork for the outer carton of Dulcolax Adult 5mg GR Tablets (pack size 20 count). The dose instruction incorrectly states for use in 12 years and older. These packs are for general sale (GSL) and are intended for use only in adult patients (18 years and over). Although the same active ingredient and strength is indicated for children 12 years and over, the alternative licensed product, Dulcolax Twelve Plus tablets ('P' pack) should only be used in children 12 years and over after consultation with a pharmacist.

Opella Healthcare UK LTD have confirmed that the batches of Dulcolax Adult 5mg GR Tablets (pack size 20 count) listed in this notification were distributed to both pharmacy and non-pharmacy retailers. However, following a discussion with the MHRA all further stock of the batches listed in this notification which have been partially distributed and those batches listed as 'Not yet distributed,' will only be provided to pharmacy stores, and several healthcare stores. Opella Healthcare UK LTD will contact the customers directly to make them aware of this issue and further supply and these batches will be distributed from 10 June 2025. Batches which are repacked into amended artwork cartons where possible, will be made available to all retailers.

Advice for Healthcare Professionals and retailers:

Healthcare professionals and retailers are advised to review the information contained within this notification and where possible, customers should be informed that Dulcolax Adult 5mg GR Tablets is approved for adult use only and to take the product as indicated in the Patient Information Leaflet (PIL) or based on advice from their healthcare professional.

Please see a link to the Patient Information Leaflet (PIL) for further information:
https://www.medicines.org.uk/emc/product/361/pil#gref

Advice for Healthcare Professionals to Provide to Patients:

Adult patients should continue to take medicines from the impacted batches. The quality of the product is not affected which is why the products are not being recalled and will remain to be available for sale.

There is an error on the back of the carton, this product is only intended for use by adults (18 years and over) and should not be used in children (under the age of 18). Ensure that you follow the information provided in the patient information leaflet.

Based on the safety assessment, it was concluded that there is no harm expected to children who may have taken this medication. Dulcolax Twelve Plus tablets ('P' pack) have the same active ingredient (Bisacodyl) and same strength (5mg) as Dulcolax Adult GR tablets ('GSL' pack).

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

Additional information:

For all medical information enquiries and information on this product, please email uk-medicalinformation@sanofi.com, or telephone 0800 035 2525.

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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