



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level

Date: 07 September 2023

EL (23)A/35

Our Ref: MDR 201-08/23

Dear Healthcare Professional,

Colgate-Palmolive (U.K.) Limited

Duraphat 5000ppm Fluoride Toothpaste (51g)

PL 00049/0050

SNOMED Code: 10770611000001106

Batch No	Expiry Date	Pack Size	First Distributed
3011FR63A1	12/2025	1	16/02/2023
3026FR63A1	12/2025	1	07/06/2023
3031FR63A1	12/2025	1	12/04/2023
3047FR63A1	01/2026	1	29/03/2023
3053FR63A1	01/2026	1	12/04/2023
3060FR63A1	02/2026	1	24/04/2023
3061FR63A1	02/2026	1	27/04/2023
3061FR63A2	02/2026	1	27/04/2023
3068FR63A1	02/2026	1	24/04/2023
3082FR63A1	02/2026	1	30/05/2023
3081FR63A1	02/2026	1	30/05/2023
3096FR63A1	03/2026	1	05/06/2023
3096FR63B1	03/2026	1	05/06/2023
3102FR63A1	03/2026	1	05/06/2023
3103FR63A1	03/2026	1	05/06/2023
3108FR63A1	03/2026	1	07/06/2023
3110FR63A1	03/2026	1	03/07/2023
3131FR63A1	04/2026	1	Not yet Distributed
3123FR63A1	04/2026	1	Not yet Distributed
3172FR63A1	05/2026	1	Not yet Distributed

Active Pharmaceutical Ingredient: Sodium Fluoride

Brief description of the problem

Colgate-Palmolive (U.K.) Limited has informed the MHRA that the Patient Information Leaflet (PIL), carton and tube of the batches of Duraphat 5000ppm Fluoride Toothpaste (51g) listed above are missing information relating to the presence of allergens in the product. In addition, the PIL is missing information relating to the concentration of Sodium Benzoate. This follows changes to the information that needs to be disclosed in product information. The impacted product, and all other batches, remain within product specification and there is no issue with product quality. To ensure that prescriptions are fulfilled and patients' access to the product is maintained, the batches on hold awaiting distribution will be sold and



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have been included in this notification for information. Colgate-Palmolive (U.K.) Ltd will work to ensure that compliant products are available as soon as possible.

Details of the wording discrepancies are listed below:

Tube/Carton	
Current text	Updated text
<p>7. OTHER SPECIAL WARNING(S) IF NECESSARY</p> <p>Do not use in adolescents and children under 16 years of age.</p> <p>Contains Sodium Benzoate.</p>	<p>7. OTHER SPECIAL WARNING(S) IF NECESSARY</p> <p>Do not use in adolescents and children under 16 years of age.</p> <p>Contains Sodium Benzoate. <i>Sodium Benzoate may cause local irritation.</i></p> <p><i>This medicine contains a flavouring with limonene, linalool, citral, geraniol, and citronellol which may cause allergic reactions.</i></p>

Product Information Leaflet	
Current text	Updated text
<p>2. BEFORE YOU USE DURAPHAT® TOOTHPASTE</p> <p>Important information about some of the ingredients of Duraphat® Toothpaste</p> <p>This toothpaste contains Sodium Benzoate. Sodium Benzoate is a mild irritant to the skin, eyes, and mucous membrane.</p>	<p>2. BEFORE YOU USE DURAPHAT® TOOTHPASTE</p> <p>Important information about some of the ingredients of Duraphat® Toothpaste</p> <p>This medicine contains 5mg sodium benzoate in each g of toothpaste. Sodium Benzoate may cause local irritation.</p> <p>This medicine contains a flavouring with limonene, linalool, citral, geraniol, and citronellol which may cause allergic reactions.</p>

Advice for healthcare professionals

Healthcare professionals are advised to note the updated information. Where appropriate, inform patients about it, provide them with an updated copy of the PIL, and remind them to read the leaflet in its entirety before using the medicine. This notification relates to multiple batches and there is no expectation that you contact patients directly.

Upon request, the manufacturer will post hard copies of the updated PIL to wholesalers and pharmacies so that any remaining stock in the dispensary can be supplemented with the correct PIL information. Contact Colgate-Palmolive's customer contact facilities (00800 321 321 32) to request hard copies.



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The correct PIL is also available via <https://www.colgate.com/en-gb/products/specialty/duraphat-product-labelling-update> to enable healthcare professionals to provide it to patients directly.

The manufacturer has confirmed that the batches that have yet to be distributed will be accompanied by a note explaining the issue along with a copy of the correct PIL, to supplement dispensing at pharmacies. These batches will not be repackaged to avoid any supply concerns. The manufacturer has confirmed that all future batches will be packaged with the correct PIL.

Advice for patients

Patients should be aware that batches of Duraphat 5000ppm Fluoride Toothpaste (51g) are missing important safety information after changes were made to the information that needs to be included. The Patient Information Leaflet (PIL), carton and tube of the product do not include information about the presence of allergens in the product, and the PIL is missing information relating to the concentration of Sodium Benzoate.

You can access the updated PIL via <https://www.colgate.com/en-gb/products/specialty/duraphat-product-labelling-update>. Patients can request a copy of the updated PIL or ask questions about the product by contacting Colgate-Palmolive's customer contact facilities on 00800 321 321 32 or via <https://www.colgatepalmolive.co.uk/contact-us>

Patients should continue to use the impacted batches of Duraphat 5000ppm Fluoride Toothpaste (51g) as prescribed. If you have any questions about your medicine or are concerned about side effects, talk to your healthcare professional.

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 enquiries or stock control enquiries please contact Colgate-Palmolive (UK) Limited on 00800 321 321 32 or <https://www.colgatepalmolive.co.uk/contact-us>

Recipients of this notice 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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