



## Medicines Colour Classification Change Proposal Duraphat / sodium fluoride 1.1% toothpaste

**Indication: Treatment of head and neck cancer patients who have had surgery, radiotherapy and/or chemotherapy**

**Recommendation: GREEN (restricted)**

**Appropriate for initiation and ongoing prescribing in both primary and secondary care provided:**

**Additional criteria specific to the medicine or device are met, or**

**The medicine or device is used following the failure of other therapies as defined by the relevant LSCMMG pathway.**

**Generally, little or no routine drug monitoring is required.**

**MLCSU recommends a GREEN (restricted) RAG rating for the use of 1.1% sodium fluoride toothpaste in head and neck cancer patients on advice from a secondary care specialist, who have had surgery, radiotherapy and/or chemotherapy, who are unable to access a primary care dentist.**

This is in agreement with:

Pan Mersey APC: Guidance for dental prescribing in primary care states: Mouthwashes and toothpaste are DENTAL prescription only; long term treatment should be under their usual dentist. However they may be prescribed on advice from secondary care specialists e.g. following radiotherapy during active management, haematological malignancies or oral dermatological diseases.

Pan Mersey APC<sup>1</sup> gives Duraphat – 1.1% sodium fluoride toothpaste an AR rating (requires specialist assessment to enable patient selection) for patients on advice from secondary care specialists e.g. following radiotherapy during active management, haematological malignancies or oral dermatological diseases. A Black rating is given for dental prescription for conditions managed by dentists; long term treatment should be under patient's usual dentist, and toothpaste prescribed by the dentist.

GMMMG<sup>2</sup> gives Duraphat – 1.1% sodium fluoride toothpaste a GREY / GREEN (Specialist Advice) RAG Rating for patients at risk of caries secondary to treatment for head and neck cancers or reduced salivary flow rate secondary to surgery. To be continued for as long as natural teeth remain. The prescribing of fluoride mouthwashes and toothpastes for other indications should be by dental prescription only

### **Summary of supporting evidence:**

- British Association of Head and Neck Oncologists (BAHNO) Standards 2021 Page 32<sup>3</sup>. 'ALL dentate individuals should have high concentration of fluoride toothpaste prescribed. This is national standards for best practice in the UK. [https://bahno.org.uk/clinicians\\_area/publications.aspx](https://bahno.org.uk/clinicians_area/publications.aspx)
- The Oral Management of Oncology Patients Requiring Radiotherapy, Chemotherapy and / or Bone Marrow Transplantation Clinical guidelines' 2018 Royal College of Surgeons<sup>4</sup>. 'The following fluoride content of toothpaste is recommended for patients giving concern to the dentist (e.g. those with active caries, dry mouth and other predisposing factors which may be linked to cancer therapy) (Public Health England, 2017) Adolescents / adults aged 16 years old and over: 2800ppm - 5000ppm' <https://www.rcseng.ac.uk/dental-faculties/fds/publications-guidelines/clinical-guidelines/>

- Delivering better oral health: an evidence-based toolkit for prevention Public Health England Nov 2021<sup>5</sup> 'Sodium fluoride 5,000 ppm toothpaste Indications for use: include high dental caries risk patients aged 16 years and over. This includes those with root or coronal caries present or risk factors such as dry mouth, overdentures, those with a highly cariogenic diet or cariogenic medication and those who have received head and neck radiotherapy and chemotherapy' <https://www.gov.uk/government/publications/delivering-better-oral-health-an-evidence-based-toolkit-for-prevention>

## Details of Review

<b>Name of medicine</b> (generic & brand name) Duraphat / 1.1% sodium fluoride toothpaste
<b>Strength(s) and form(s):</b> 1 x 51g tube of 1.1% sodium fluoride toothpaste (1 g of toothpaste contains 5 mg fluoride, corresponding to 5000ppm fluoride).
<b>Dose and administration:</b> Duraphat® / Sodium Fluoride 1.1% Toothpaste is used 3 times a day for brushing your teeth, apply a 2 cm ribbon onto your toothbrush for each brushing (2 cm provides between 3 mg and 5 mg of fluoride).
<b>BNF therapeutic class / mode of action:</b> Dental
<b>Licensed indication(s):</b> Fluoride 1.1% / 5000 ppm Toothpaste is indicated in adults and adolescents aged 16 years and over. Prevention of dental caries in adolescents and adults, particularly amongst patients at risk from multiple caries (coronal and / or root caries).
<b>Proposed use</b> (if different from, or in addition to, licensed indication above): Specifically for head and neck cancer patients who have had surgery, radiotherapy and/or chemotherapy
<b>Course and cost:</b> Ongoing. £5.24 for 51g <sup>6</sup>
<b>Current standard of care/comparator therapies:</b> Duraphat <sup>7</sup> (marketed by Colgate) and a generic Sodium Fluoride 1.1% toothpaste <sup>8</sup> (marketed by Morningside Healthcare Ltd) are available

## Background and context

LSCMMG currently have Fluorides with a RED RAG rating, with the recommendation that high concentration fluoride toothpaste is only prescribed by General Dental Practitioners.

A consultant in Restorative Dentistry at Lancashire Teaching Hospital (LTH) has requested that this RAG rating is reviewed specifically for Head and neck cancer patients who have had surgery, radiotherapy and/or chemotherapy are often left with severely dry mouths, restricted mouth opening, and reduced access for toothbrushing or professional dental care.

Due to the difficulties of maintaining their weight and chewing following their treatment, their diet is often highly calorific and sugary, soft and sticky. As a result of their cancer treatment they have, and will always have, a high risk of dental decay and gum disease. Dental decay in these patients is often rapidly progressing and rampant. In many situations there is no alternative other than extraction of teeth.

Due to the effects of radiotherapy on the jawbone, patients from this cohort who are requiring extraction are at risk of osteoradionecrosis of the jaw bone. Osteoradionecrosis itself can be a painful condition that is incredible difficult to treat and may result in further surgery, at its most severe it might include further resection of the jaw. The effects of this on patients' quality of life is catastrophic.

Duraphat / sodium fluoride 1.1% toothpaste, has a higher fluoride content and is an essential tool in offsetting the risk of dental decay in this patient group, along with fluoride mouthwash and topical varnish. It is advised in national recommendations that these patients remain on this for life. Unfortunately, many patients who suffer with head and neck cancer are non-dental attenders and are not registered with a primary care dentist.

Although these patients are advised to register with a dentist as soon as possible, the current situation of dental healthcare in the UK is such that accessing primary care dentists is very difficult indeed.

Unfortunately, the small team at LTH of 1 full time and 1 part time consultants in Restorative dentistry, are not able to provide routine dental care that should be performed in primary care dental practice. Nor can they see these patients in the longer term for repeated prescriptions of toothpaste.

The current situation whereby the medication is not available on the GP formulary (RED RAG rating) leaves these patients in a situation whereby they are not able to access this medication.

A change in RAG rating to Green (Restricted) specifically for this patient cohort would enable it to be prescribed on a repeat prescription by GPs (where not available via an NHS dentist) and allow these specific patients access to this medication.

## Summary of evidence

### Summary of efficacy data in proposed use:

Reversal of primary root caries using dentifrices containing 5,000 and 1,100 ppm fluoride  
Baysan A, et al. Caries Res. 2001;35:41-46.<sup>9</sup>

This study compared the ability of two sodium fluoride dentifrices, one containing 5,000 ppm fluoride (Prevident 5000 Plus) and the other 1,100 ppm fluoride (Winterfresh Gel), to reverse primary root caries lesions (PRCLs). A total of 201 subjects with at least one PRCL each entered the study and were randomly allocated to use one of the dentifrices. After 6 months, 186 subjects were included in statistical analyses. At baseline and after 3 and 6 months, the lesions were clinically assessed and their electrical resistance measured using an electrical caries monitor. After 3 months, 39 (38.2%) of the 102 subjects in the 5,000 ppm F- group and 9 (10.7%) of 84 subjects using the 1,100 ppm F- dentifrice, had one or more PRCLs which had hardened ( $p = 0.005$ ). Between baseline and 3 months, the log<sub>10</sub> mean  $\pm$  SD resistance values of lesions for subjects in the 1,100 ppm F- group had decreased by 0.06 $\pm$ 0.55, whereas those in the 5,000 ppm F- group had increased by 0.40 $\pm$ 0.64 ( $p < 0.001$ ). After 6 months, 58 (56.9%) of the subjects in the 5,000 ppm F- group and 24 (28.6%) in the 1,100 ppm F- group had one or more PRCLs that had become hard ( $p = 0.002$ ). Between baseline and 6 months, the log<sub>10</sub> mean  $\pm$  SD resistance values of lesions for subjects in the 1,100 ppm F- group decreased by 0.004 $\pm$ 0.70, whereas in the 5,000 ppm F- group, they increased by 0.56 $\pm$ 0.76 ( $p < 0.001$ ). After 3 and 6 months, the distance from the apical border of the root caries lesions to the gingival margin increased significantly in the 5,000 ppm F- group when compared with the 1,100 ppm F- group. The plaque index in the 5,000 ppm F- group was also significantly reduced when compared with the 1,100 ppm F- group. The colour of the lesions remained unchanged. It was concluded that the dentifrice containing 5,000 ppm F- was significantly better at remineralising PRCLs than the one containing 1,100 ppm F-.

### Summary of safety data :

This toothpaste has a high fluoride content. Therefore, the opinion of a dental specialist must be sought before the product is used.

An increased number of potential fluoride sources may lead to fluorosis. In order to prevent the accumulation of fluoride, the total fluoride intake must be assessed before this fluoride toothpaste is ever used. Fluoride tablets, drops, chewing gum, gel or varnishes, and fluoridated water or salt should be avoided during use of Fluoride 5000 ppm Toothpaste.

When carrying out overall calculations of the recommended fluoride ion intake, which is 0.05 mg / Kg body weight per day from all sources, not exceeding 1 mg per day, allowance must be made for possible ingestion of toothpaste (each 51 g tube of Fluoride 5000 ppm Toothpaste contains 225 mg of fluoride ions).

This product contains sodium benzoate. Sodium benzoate is a mild irritant to the skin, eyes, and mucous membrane.

This product contains sorbitol solution. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

This product contains propylene glycol. Propylene glycol may cause skin irritation.

This product should not be used by children and adolescents aged under sixteen years,

### Prescribing and risk management issues:

N/A

### Commissioning considerations:

**Innovation, need and equity implications of the intervention:**

1.1% (5000ppm) Sodium Fluoride toothpaste is available for prescribing within Primary Care in both GMMM and Pan Mersey under specialist advice.

The current situation of dental healthcare in the UK is such that accessing primary care dentists is very difficult, leaving these patients without access to the higher fluoride content toothpaste in Lancashire and South Cumbria.

**Financial implications of the intervention:**

NHS list price of 1 x 51g tube = £5.24

1 g of toothpaste contains 5 mg fluoride, corresponding to 5000ppm fluoride.

According to the manufacturers a 2 cm ribbon provides between 3 mg and 5 mg of fluoride ie approximately 1g of toothpaste.

Recommended usage is 2cm three times a day ie approx.3g / day, therefore a 51g tube should last approximately 17 days.

Annual use per patient will therefore equate to approximately 22 tubes = £115.28 / year.

The requesting consultant has stated that numbers can vary in how many new patients they see a month, but approximately – 90-180 over the year. However, **not** all these patients will receive 1.1% sodium fluoride toothpaste.

90 patients a year prescribed the toothpaste would result in an annual approximate cost of £10,375.20

180 patients a year prescribed the toothpaste would result in an annual approximate cost of £20,750.40

**Service Impact Issues Identified:**

N/A

**Equality and Inclusion Issues Identified:**

None anticipated.

**Cross Border Issues Identified:**

Pan Mersey APC Formulary have given 1.1% sodium fluoride toothpaste an AMBER Recommended (AR) RAG rating for patients on advice from secondary care specialists e.g. following radiotherapy during active management, haematological malignancies or oral dermatological diseases. Amber Recommended medicines must meet criteria: (1) Requires specialist assessment to enable patient selection (2) Following specialist assessment, the medicine is suitable for prescribing in Primary Care.

GMMM have given 1.1% sodium fluoride toothpaste a GREY / GREEN (Specialist Advice) RAG Rating for patients at risk of caries secondary to treatment for head and neck cancers or reduced salivary flow rate secondary to surgery. To be continued for as long as natural teeth remain. GREY - Products which are not suitable for routine prescribing, but suitable for exceptional use in a defined patient population. Prescribers should ensure that more suitable alternatives have been considered and ruled out as not being appropriate before recommending or prescribing a medicine with a GREY list status. In these cases a RAG of RED, AMBER or GREEN will also be assigned to clarify in which care setting prescribing responsibility lies. GREEN (Specialist Advice) - Drugs that are suitable for initiation by primary care following written or verbal advice from a specialist service. Little or no monitoring is required.

<b>Legal Issues Identified:</b>
None identified.
<b>Media/ Public Interest:</b>
N/A

## References

- 
- <sup>1</sup> Pan Mersey APC Formulary - <https://formulary.panmerseyapc.nhs.uk/chaptersSubDetails.asp?FormularySectionID=9&SubSectionRef=09.05.03&SubSectionID=A100&drugmatch=2283#2283> .
  - <sup>2</sup> GMMMG Formulary Chapter 9 – page 12 of 17. <https://gmmmg.nhs.uk/joint-formulary/gmmmg-formulary-chapters/>
  - <sup>3</sup> British Association of Head and Neck Oncologists (BAHNO) Standards 2021 Page 32 [https://bahno.org.uk/clinicians\\_area/publications.aspx](https://bahno.org.uk/clinicians_area/publications.aspx)
  - <sup>4</sup> The Oral Management of Oncology Patients Requiring Radiotherapy, Chemotherapy and / or Bone Marrow Transplantation Clinical guidelines' 2018 Royal College of Surgeons. <https://www.rcseng.ac.uk/dental-faculties/fds/publications-guidelines/clinical-guidelines/>
  - <sup>5</sup> Delivering better oral health: an evidence-based toolkit for prevention Public Health England Nov 2021. <https://www.gov.uk/government/publications/delivering-better-oral-health-an-evidence-based-toolkit-for-prevention>
  - <sup>6</sup> Drug Tariff August 2023. <https://www.drugtariff.nhsbsa.nhs.uk/#/00841024-DC/DD00840924/Part%20VIII%20products%20S>
  - <sup>7</sup> Colgate: professional content - <https://www.colgateprofessional.com.hk/products/products-list/colgate-5000-duraphat>
  - <sup>8</sup> EMC: Fluoride 5000 ppm Toothpaste <https://www.medicines.org.uk/emc/product/9575/smpc>
  - <sup>9</sup> Reversal of primary root caries using dentifrices containing 5,000 and 1,100 ppm fluoride. Baysan A, et al. Caries Res. 2001;35:41-46 <https://pubmed.ncbi.nlm.nih.gov/11125195/>