

# Prescribing high fluoride toothpaste for caries prevention

## Page notes

Colgate® is committed to a cavity free future. This ECPD programme reviews the latest NHS prescribing guidance to clarify the role and use of dental prescriptions in providing evidence-based caries control for your patients.

**Slide 1**



Next slide

# Aim and learning outcomes

**Aim:** To provide an overview of the CCG prescribing guidance for OTC products and to clarify the role and use of dental prescriptions for caries prevention in primary care.

## Learning outcomes:

- Understand the scope and limitation of the OTC prescribing guidance
- Review patient and clinical factors for increased caries risk
- Review the indications and clinical effectiveness of Colgate® Duraphat® Fluoride Toothpastes

**Anticipated GDC development outcome:** C



## Page notes

Please review the aim and learning outcomes.



Previous slide

**Slide 2**



Next slide





# Contents

- Review new guidance for CCG's on over the counter (OTC) prescribing for caries prevention in primary care
- Review patient and clinical factors for increased caries risk
- Prescribing high fluoride toothpaste for increased risk patient groups
- Link to ECPD survey for up to 1-hour ECPD

## Page notes

The content of this presentation covers prescribing for caries prevention in primary care.

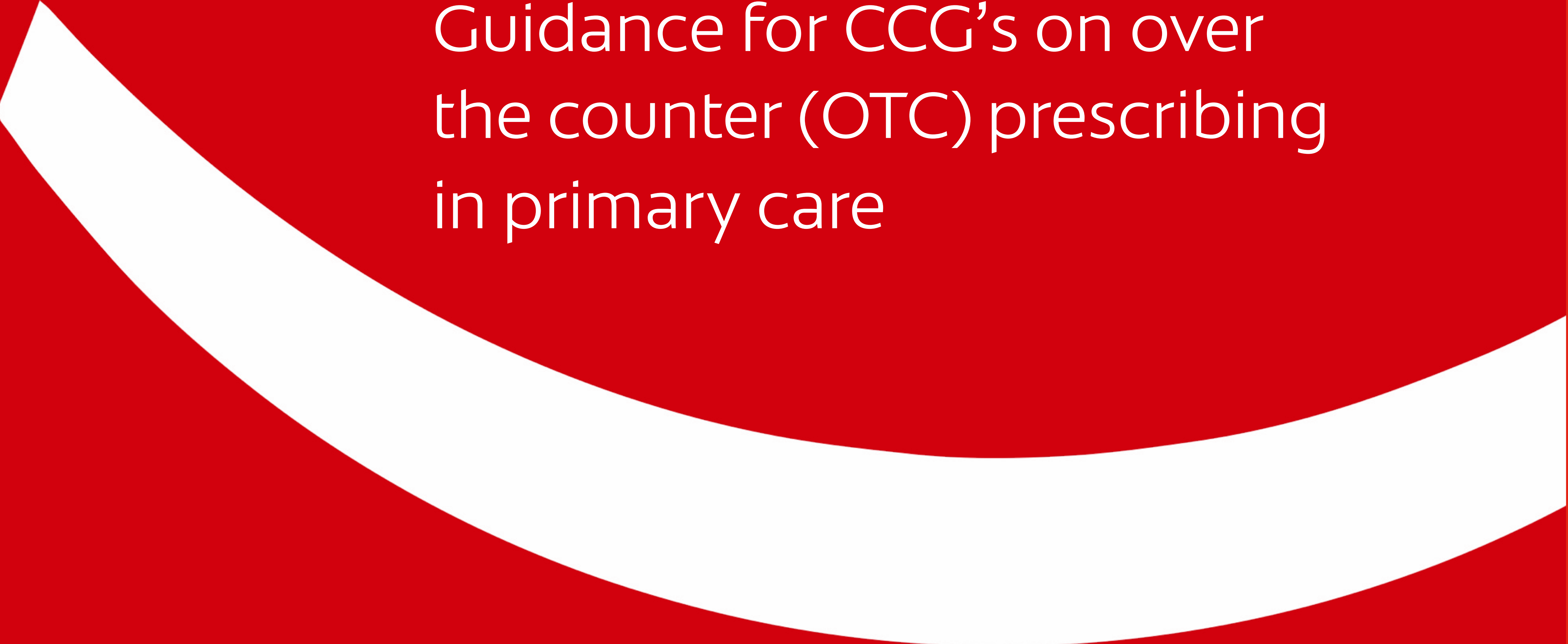


Previous slide

**Slide 3**



Next slide



# Guidance for CCG's on over the counter (OTC) prescribing in primary care

## Page notes



Previous slide

**Slide 4**

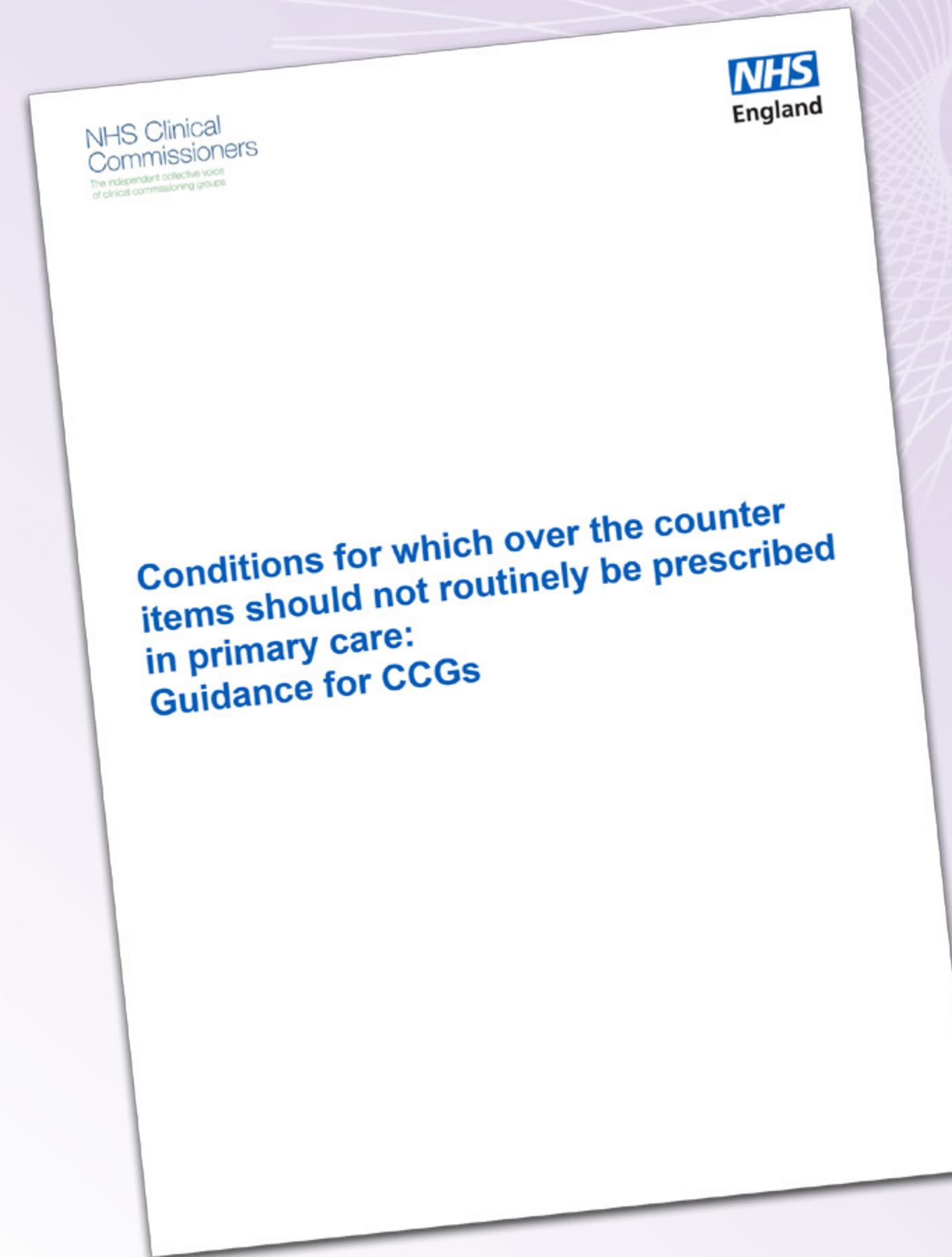


Next slide



# New guidance to reflect local policies in prescribing practice

New guidance for CCGs on the conditions for which over the counter items should not routinely be prescribed in primary care



## Page notes

This latest guidance is for Clinical Commissioning Groups (CCGs).

It outlines the proposed conditions for which over the counter items should not routinely be prescribed in primary care. This guidance supports formulation of local policies, and for prescribers to reflect local policies in their prescribing practice.





# Focused on reducing the number of prescriptions

These prescriptions include items for minor conditions:

- which are self-limiting and heal of their own accord so don't need treatment
- which lend themselves to self-care, i.e. the person suffering does not normally seek medical advice but may decide to seek help from a local pharmacy for symptom relief and use an over the counter (OTC) medicine

Or items:

- for which there is limited evidence of clinical effectiveness

## Page notes

The purpose of this guidance is to reduce spend on treating conditions that are self-limiting or which lend themselves to self-care, or on items for which there is little evidence of clinical effectiveness.

These resources can be used for other higher priority areas that have a greater impact for patients, support improvements in services and/or deliver transformation that will ensure the long-term sustainability of the NHS.

The focus is on reducing prescriptions for over the counter (OTC) medicines or items that have limited evidence of clinical effectiveness.

Before we look at how this guidance classifies prevention of dental caries let's revisit classification of medicines.



Previous slide

**Slide 6**



Next slide



# Categories of medicines

The medicines act of 1968 defines three categories of medicines:

- Prescription Only Medicine (POM) – available only from a pharmacist if prescribed by an appropriate practitioner
- Pharmacy Medicine (P) – available only from a pharmacist but without a prescription
- General Sales List (GSL) – medicines which may be bought from any shop without a prescription

P and GSL medicines are classed as Over the Counter (OTC) products

## Page notes

The medicines act identifies medicines that are available over the counter

Prescription Only Medicines (POM) - Only available on prescription

Pharmacy Medicines P – No prescription required so available over the counter (OTC)

General Sales List – No prescription required so available over the counter (OTC)

P and GSL medicines are classed as Over the Counter (OTC) products



Previous slide

**Slide 7**



Next slide



# Caries prevention - minor condition suitable for self-care

## 4.3.22 Prevention of dental caries

Annual Spend	c.< £100, 000
Rationale for recommendation	The dentist may advise on using higher-strength fluoride toothpaste if you are particularly at risk of tooth decay. Some higher fluoride toothpastes (~1500 ppm) and mouthwashes can be purchased over the counter.
References:	1. <a href="#">NHS Choices: Tooth Decay accessed October 2017.</a> 2. <a href="#">PrescQIPP: Dental products</a>
Recommendation	Advise CCGs that a prescription for high fluoride OTC toothpaste should not routinely be offered in primary care as the condition is appropriate for self-care.
Exceptions	No routine exceptions have been identified. See earlier for general exceptions.

Conditions for which over the counter items should not routinely be prescribed Guidance for CCGs, NHS England, March 2018, Page 31

## Page notes

Within the guidance 'prevention of dental caries' has been listed under minor conditions suitable for self care. Other conditions such as dandruff, earwax and head lice are also included in this section.

This slide shows the information included for dental caries. The next slide shows the reason (rationale for recommendation) for including this under the minor conditions suitable for self care section and the implications for general dental practice.



Previous slide

**Slide 8**



Next slide



# Caries prevention – rationale for recommendation to CCG's

Rational for recommendation

The dentist may advise on using higher-strength fluoride toothpaste if you are particularly at risk of tooth decay. Some higher fluoride toothpastes (~1500 ppm) and mouthwashes can be purchased over the counter.

- The UK upper concentration for a fluoride toothpaste to be available OTC is 1500 ppm fluoride. The evidence-based guidance for caries prevention<sup>1</sup> states:
  - All adults and children aged 7 and over should use a toothpaste containing between 1350 ppm – 1500 ppm fluoride so available OTC
  - Those adolescents (10 years +) and adults (16 years +) who are at higher risk of caries should have a high fluoride toothpaste – high fluoride toothpaste is a POM so not available OTC

1. Delivering better oral health, Public Health England, 2014

## Page notes

Within the UK the upper limit for a fluoride toothpaste to be available OTC is 1500 ppm fluoride. Those toothpastes with a GSL license can be purchased in supermarkets and even petrol stations.

The evidence-based guidance<sup>1</sup> states all adults and children aged 7 and over should use a toothpaste containing between 1350 ppm – 1500 ppm fluoride. For those patients who are at higher risk and giving concern the evidence-base is for a high fluoride toothpaste higher than 1500 ppm. This means these higher fluoride toothpastes are only available on prescription (POM) so outside the 'rationale for recommendation' within this OTC prescribing guidance.



Previous slide

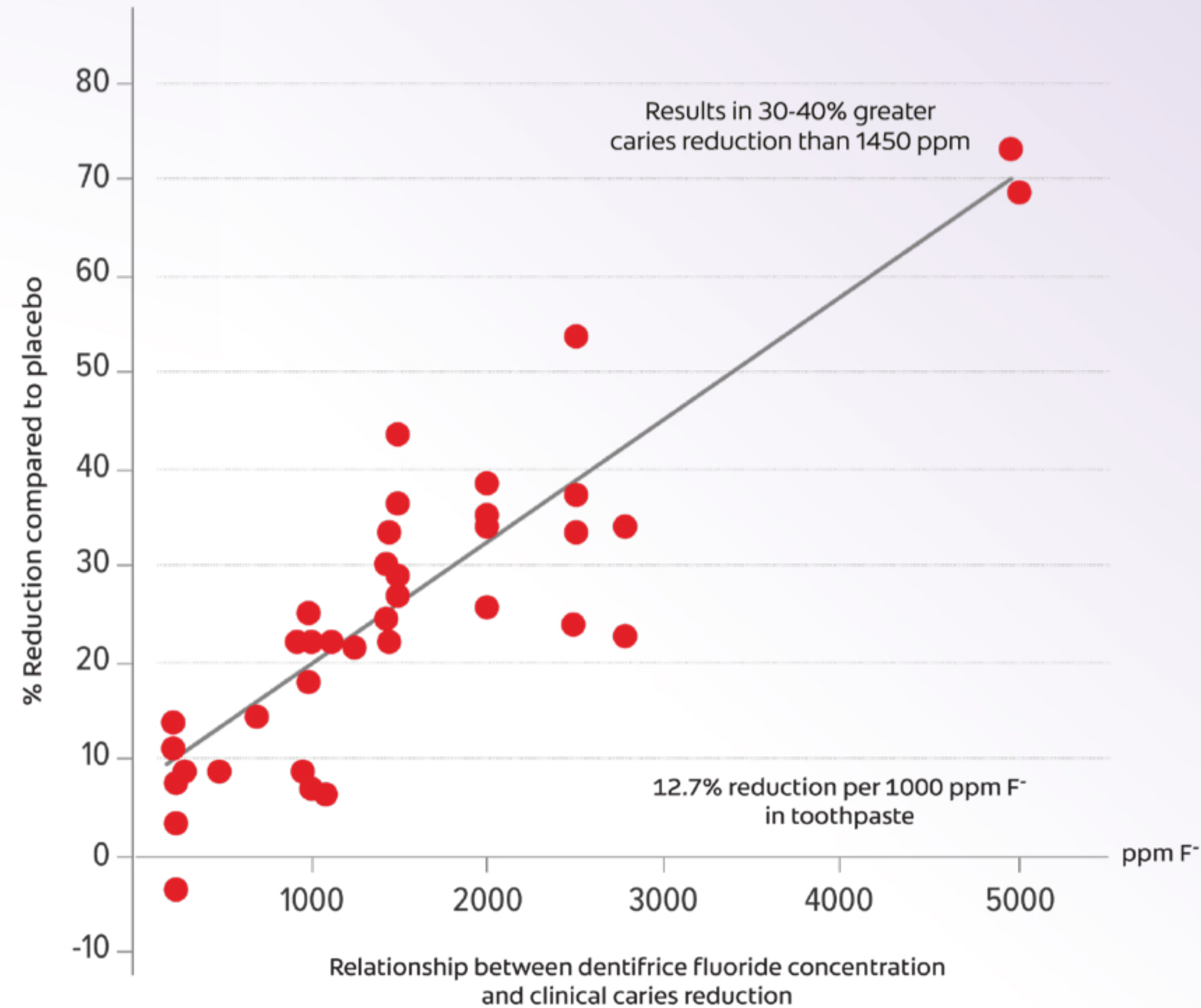
**Slide 9**



Next slide



# Fluoride concentration and clinical caries reduction



There is a clear relationship between **fluoride concentration** and **caries reduction**<sup>1</sup>

1. Tavss et al. Am J Dent, Vol 16, No 6, Dec 2003

## Page notes

With the increase in fluoride concentration there is a clear relationship with caries reduction<sup>1</sup>. As you can see in the graph on the left, as the fluoride concentration increases from 0ppm to 5000ppm F-, the caries reduction increases. In order to increase fluoride availability in your patients, you can prescribe high fluoride toothpaste.

This is outside the limitation of this OTC prescribing guidance.



Previous slide

## Slide 10



Next slide



# Caries prevention – recommendation to CCG's

Recommendation	Advise CCGs that a prescription for high fluoride OTC toothpaste should not routinely be offered in primary care as the condition is appropriate for self-care.
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- This recommendation is limited to OTC toothpastes i.e. maximum concentration of 1500 ppm fluoride
- The CCG guidance document also includes 'General Exceptions' which includes:
  - Patients on prescription only (POM) treatments
- As toothpastes containing over 1500 ppm fluoride are POM medicines, they are outside the scope of recommendation for OTC prescribing

## Page notes

Again, this recommendation is limited to OTC toothpastes, so it is only applicable for toothpaste with up to 1500 ppm fluoride.

The CCG guidance document also includes 'General Exceptions' which includes patients on prescription only (POM) treatments. As toothpastes containing over 1500 ppm fluoride are POM medicines, they are outside the scope of this CCG recommendation for OTC prescribing. Dentists should continue to prescribe high fluoride toothpastes (2800 ppm and 5000 ppm fluoride) to those patients giving concern, in line with the evidence-based guidance.



# Reviewing patient and clinical factors for increased caries risk

## Page notes



Previous slide

**Slide 12**

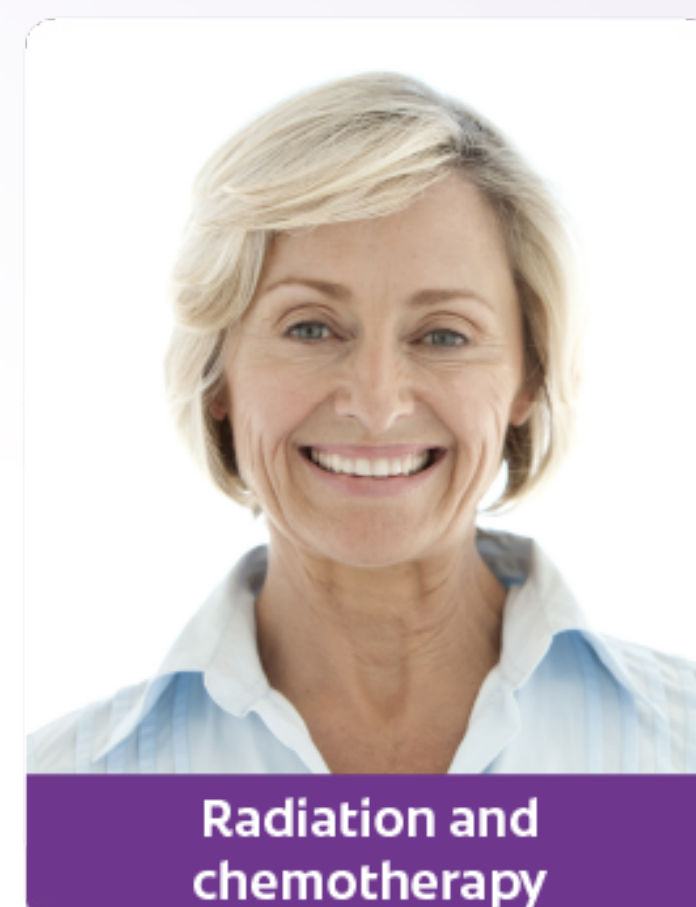
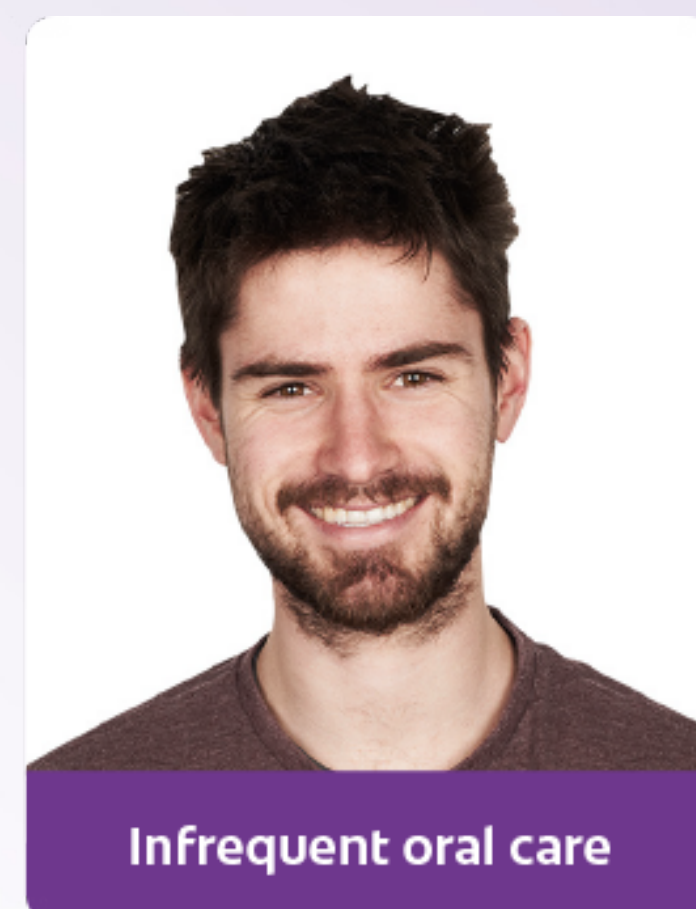


Next slide





# Patient and clinical factors increase risk of dental caries



## Page notes

A range of patient and clinical factors may increase caries risk. The evidence-based approach for patients who are giving concern is to consider prescribing high fluoride toothpaste (2800 ppm or 5000 ppm fluoride).

This guidance is included in Delivering better oral health: an evidence based toolkit for prevention, Third Edition, Public Health England, June 2014 and The Scottish Dental Clinical Effectiveness Programme (SDCEP) 2nd Edition, Published by NHS Scotland, 2018.



Previous slide

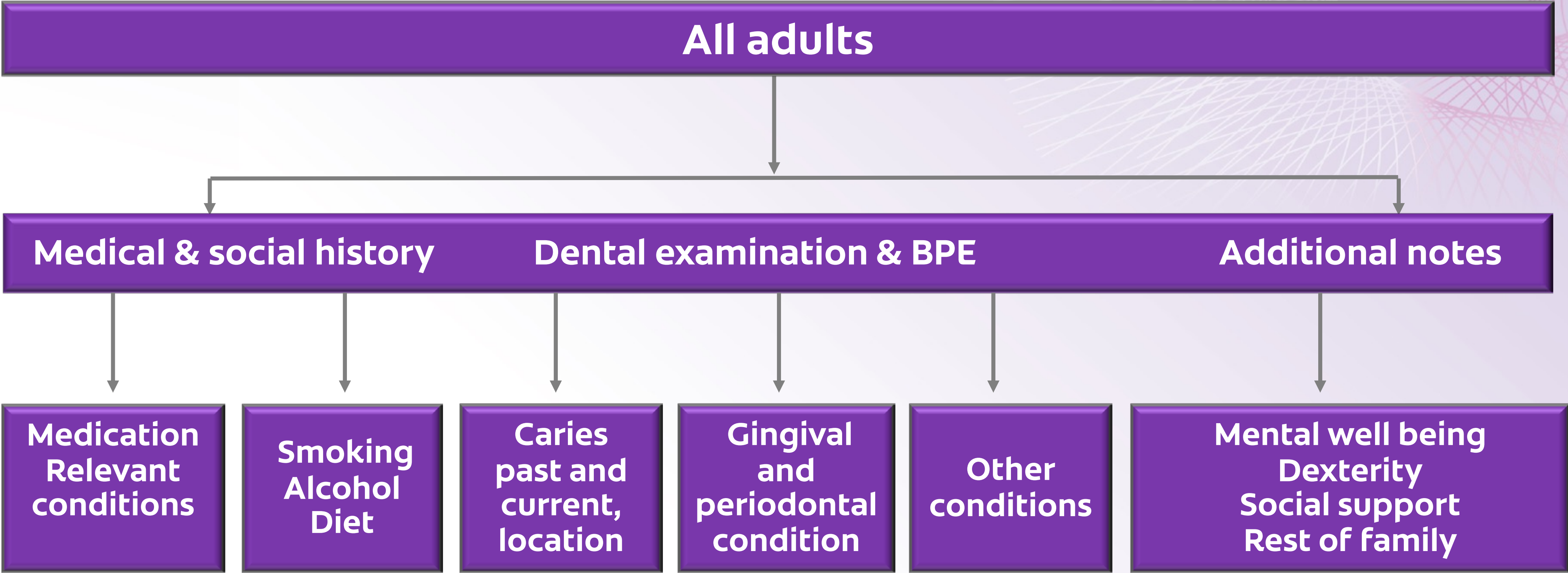
**Slide 13**



Next slide



# Identifying caries risk in adults



## Page notes

Consider your higher caries risk patients such as we have just seen for example those with obvious current active caries, dry mouth and other predisposing factors such as orthodontics or poor oral care. On reviewing these patients you gain medical and social history along with clinical information including a basic periodontal examination (BPE) anything else noteworthy for the patient or their situation.

The medical and social history give insights including medication and any relevant conditions or habits. The exam highlights any disease involvement. This combined information along with any additional notes on the patient or their situation helps to identify level of caries risk.



Previous slide

**Slide 14**



Next slide



# Prescribing high fluoride toothpaste for increased risk patient groups

## Page notes

For the purpose of this programme we are focusing on prescribing high fluoride toothpaste (2800 ppm or 5000 ppm fluoride) for increased risk patient groups. This is outside the scope of the OTC prescribing guidance. This is because they are POM toothpastes and have evidence of clinical effectiveness.



Previous slide

**Slide 15**



Next slide



# Colgate® Duraphat® 2800 ppm Fluoride Toothpaste

- Significantly superior efficacy over regular fluoride toothpaste with **20% reduction in DMFS<sup>1\*</sup>**
- Available to prescribe from the Dental Practitioners Formulary within the BNF
- Indicated for the prevention and treatment of dental caries (coronal and root) in patients aged 10 years and over with:<sup>2</sup>
  - High caries risk
  - Active caries
  - Orthodontic appliances
  - High cariogenic diet
  - Medication



1. Biesbrock AR et al. Community Dent Oral Epidemiol 2001;29:382-389. 2. Delivering better oral health: an evidence-based toolkit for prevention (2014) Public Health England \*Vs 1100 ppm fluoride toothpaste



## Page notes

Colgate® Duraphat® 2800 ppm Fluoride Toothpaste provides significantly superior efficacy over regular fluoride toothpaste with a 20% reduction in DMFS.<sup>1,\*</sup> It is indicated for the prevention and treatment of dental caries (coronal and root) in patients aged 10 years and over. DBOH recommends its use in patients giving concern including high caries risk, long term medication and a high cariogenic diet.<sup>2</sup>

Colgate® Duraphat® 2800 ppm Fluoride Toothpaste should be used to brush twice daily instead of a regular fluoride toothpaste.



Previous slide

**Slide 16**

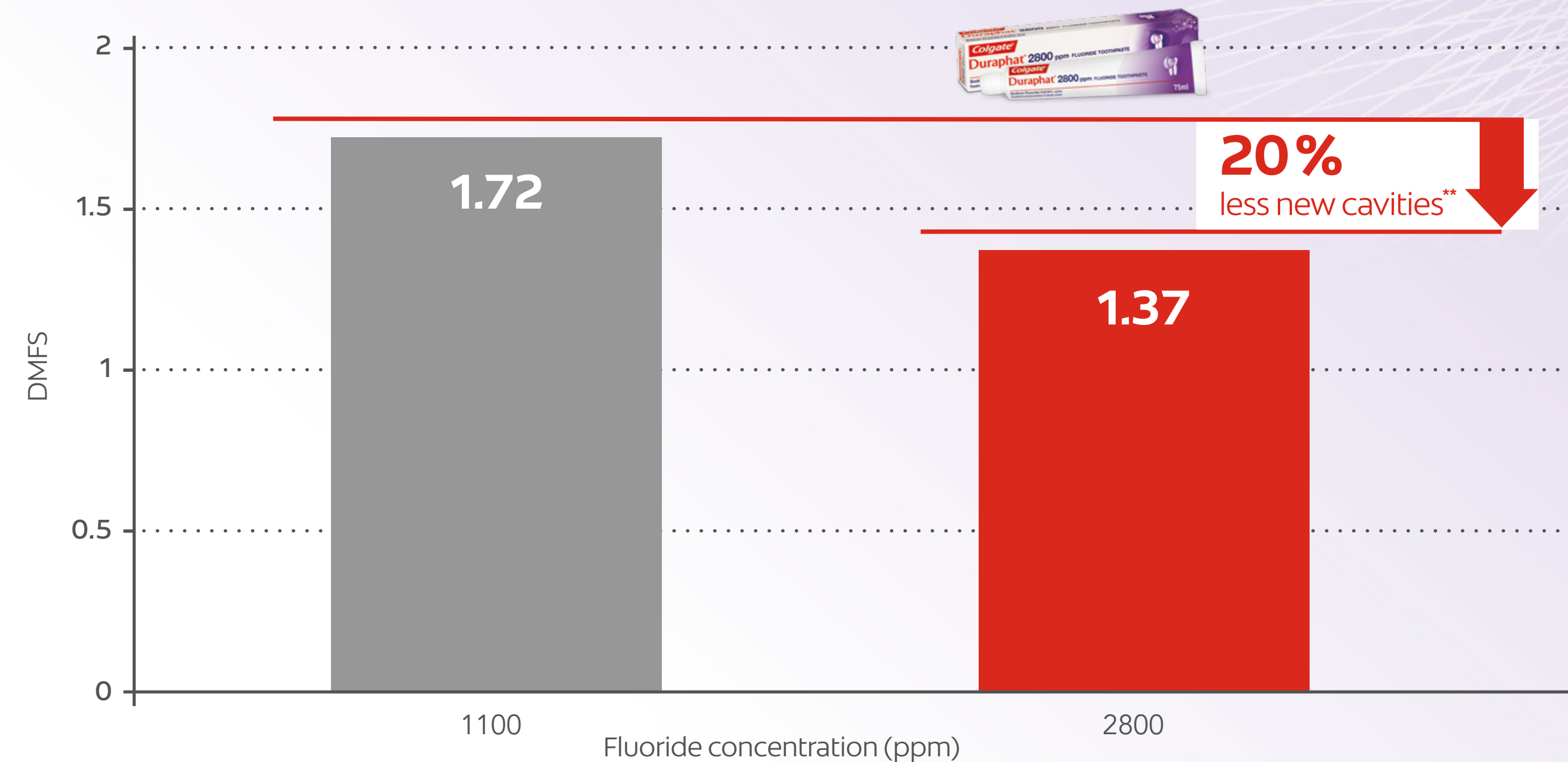


Next slide





# Colgate® Duraphat® 2800 ppm F- Toothpaste is more effective than a regular toothpaste at preventing caries<sup>1,\*</sup>



\* vs a fluoride toothpaste with 1100 ppm fluoride

\*\*After 6 months use <sup>1</sup>. Biesbrock et al. Community Dent Oral Epidemiol 2001;29:382-9.

## Page notes

This study shows a 20% reduction in DMFS when using Colgate® Duraphat® 2800 ppm Fluoride Toothpaste vs a regular fluoride toothpaste containing 1100 ppm after 6 months use.



Previous slide

**Slide 17**



Next slide





# Colgate® Duraphat® 5000 ppm Fluoride Toothpaste

- Superior anti-caries efficacy with **76% reversal in primary root caries<sup>1,\*</sup>**
- Available to prescribe from the Dental Practitioners Formulary within the BNF
- Indicated for the prevention of dental caries in adults and adolescents over 16 years, particularly amongst patients at risk from multiple caries (coronal and/or root caries) - DBOH identifies patients giving concern as:<sup>2</sup>
  - High caries risk
  - Dry mouth
  - Overdentures
  - Medication
  - Active or potential root caries
  - Orthodontic appliances
  - High cariogenic diet

\*After 6 months compared to a 1100 ppm fluoride toothpaste

1. Baysan A et al. Caries Res 2012;35:41-46. 2. Delivering better oral health: an evidence-based toolkit for prevention (2014) Public Health England.



## Page notes

Colgate® Duraphat® 5000 ppm Fluoride Toothpaste provides superior anti-caries efficacy over regular fluoride toothpaste maintained over time.<sup>1,\*</sup> It is indicated for the prevention of dental caries in adults and adolescents over 16 years, particularly amongst patients at risk from multiple caries (coronal and/or root caries). DBOH has identified patients giving cause for concern that would benefit from 5000 ppm fluoride toothpaste including patients with active or potential root caries.

Colgate® Duraphat® 5000 ppm Fluoride Toothpaste should be used instead of regular fluoride toothpaste brushing three times daily.



Previous slide

**Slide 18**

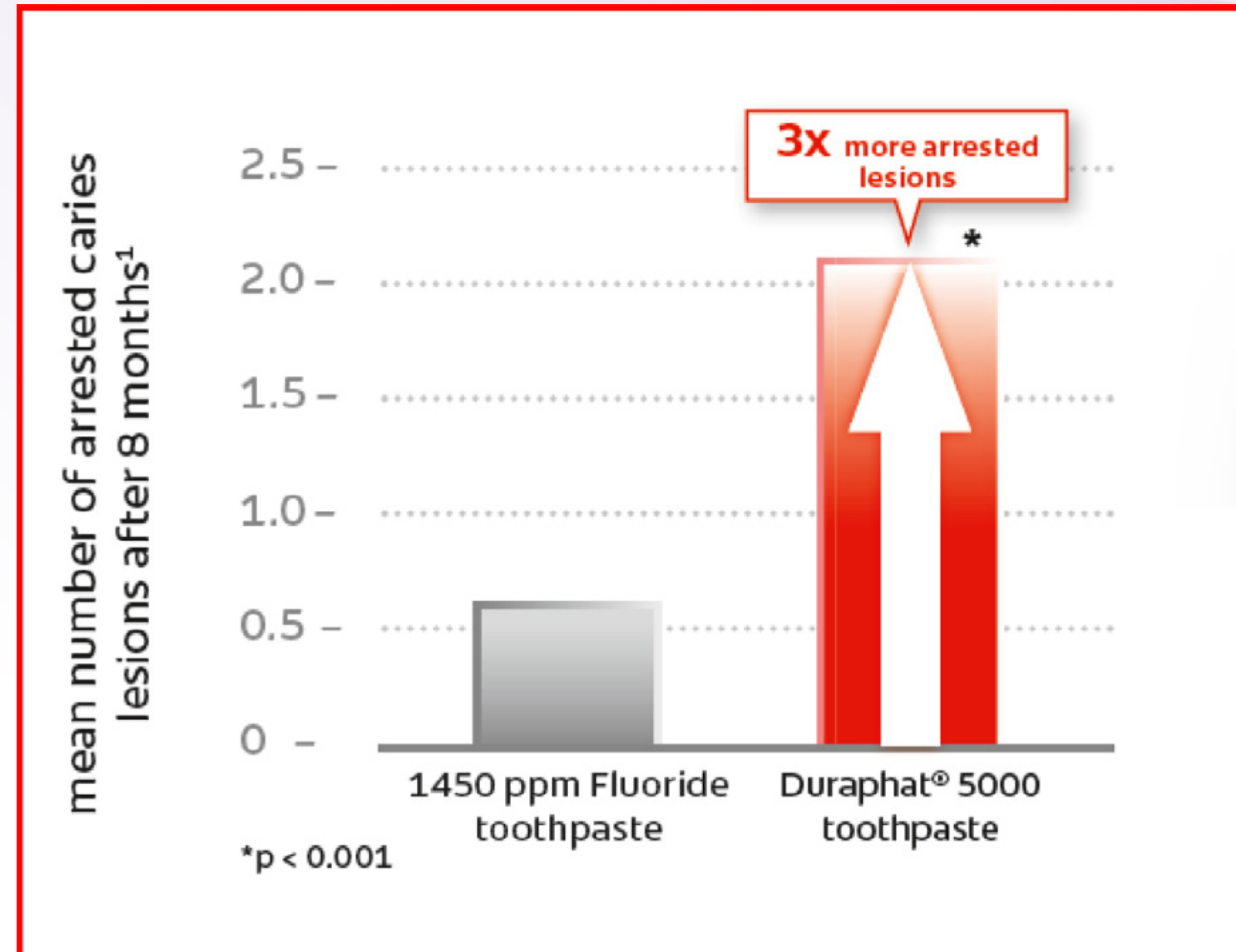


Next slide





# Clinical effectiveness - root caries lesions



Reduces 3x more arrested lesions

1. Ekstrand Gerodontology 2008; 25:67-75

## Page notes

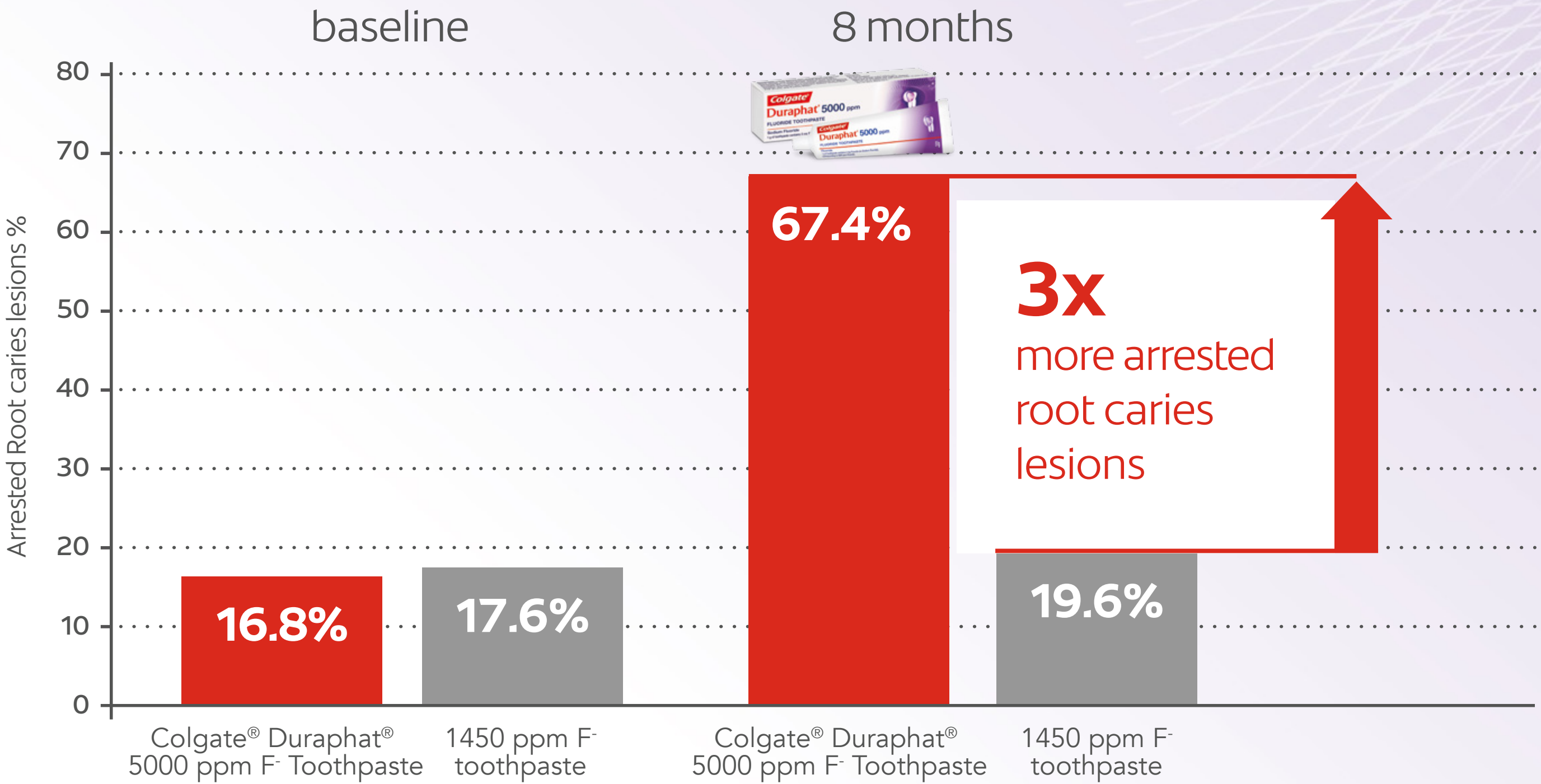
Let's now take a look at clinical evidence supporting the use of Colgate® Duraphat® 5000 ppm Fluoride Toothpaste.

This study show that Colgate® Duraphat® 5000 ppm Fluoride Toothpaste is able to arrest 3 times more root caries lesions that 1450 ppm toothpaste after 8 months of use.<sup>1</sup>



# Study in nursing-home residents confirms the benefit of Colgate® Duraphat® 5000 ppm F<sup>-</sup> Toothpaste

Colgate® Duraphat® 5000 ppm Fluoride Toothpaste delivered more effective caries prevention through controlling root caries progression\*



\* vs a regular fluoride toothpaste with 1450 ppm fluoride

Ekstrand et al. Caries Res 2013;47:391-8.

## Page notes

Again, this study looks at reductions in root caries lesions but specifically for nursing-home residents.

This study confirms the benefit of Colgate® Duraphat® 5000 ppm Fluoride Toothpaste over a regular fluoride toothpaste containing 1450 ppm fluoride in a nursing-home setting.



Previous slide

**Slide 20**

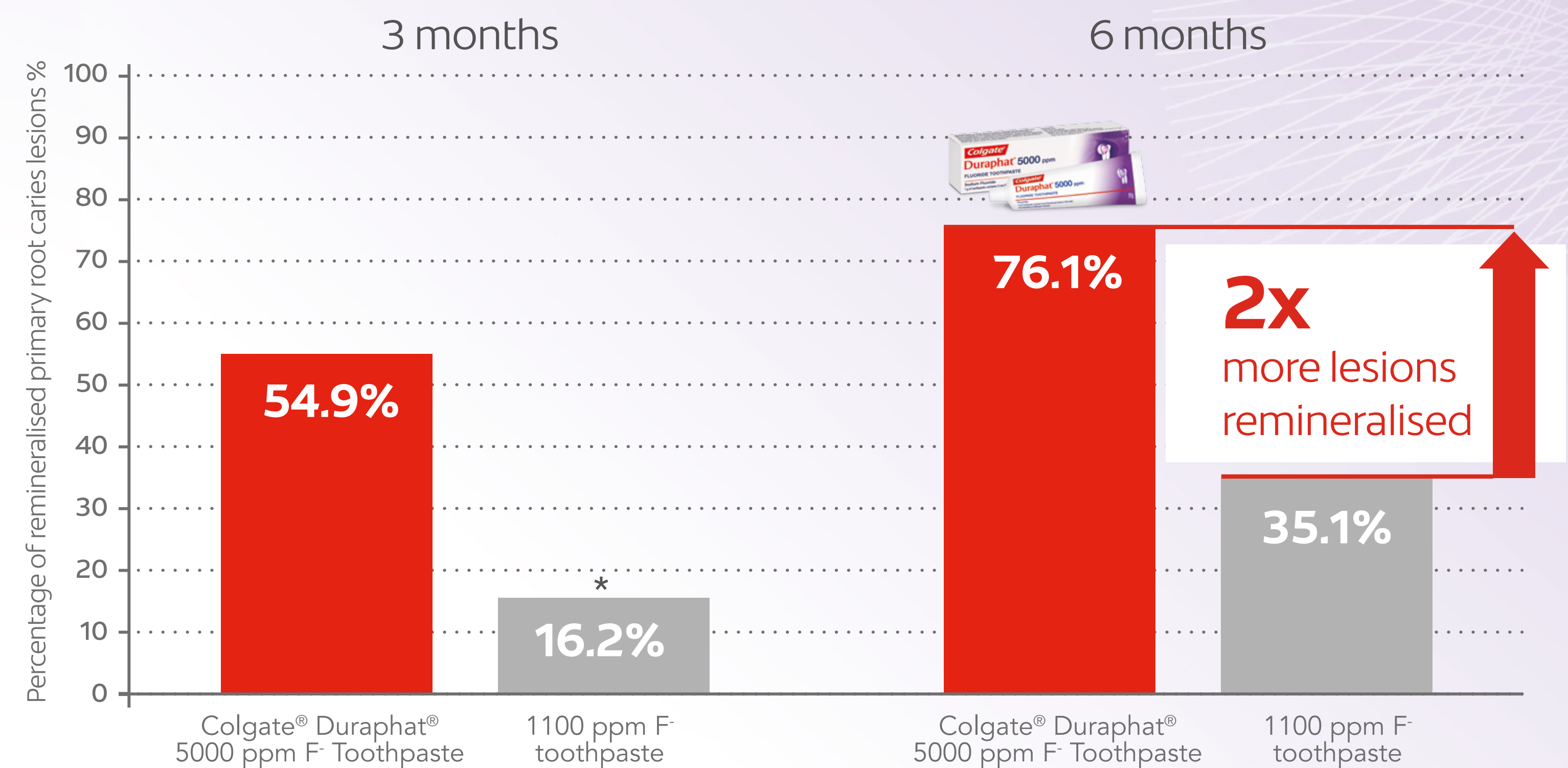


Next slide





# Colgate® Duraphat® 5000 ppm F- Toothpaste remineralises 2x more primary root caries lesions after 6 months<sup>1,#</sup>



# vs a fluoride toothpaste with 1100 ppm fluoride

\*p<0.001

1. Baysan et al. Caries Research 2001;35:41-46.

## Page notes

This study shows Colgate® Duraphat® 5000 ppm Fluoride Toothpaste remineralises 2x more primary root caries lesions after 6 months vs a regular fluoride toothpaste containing 1100 ppm fluoride.



Previous slide

Slide 21

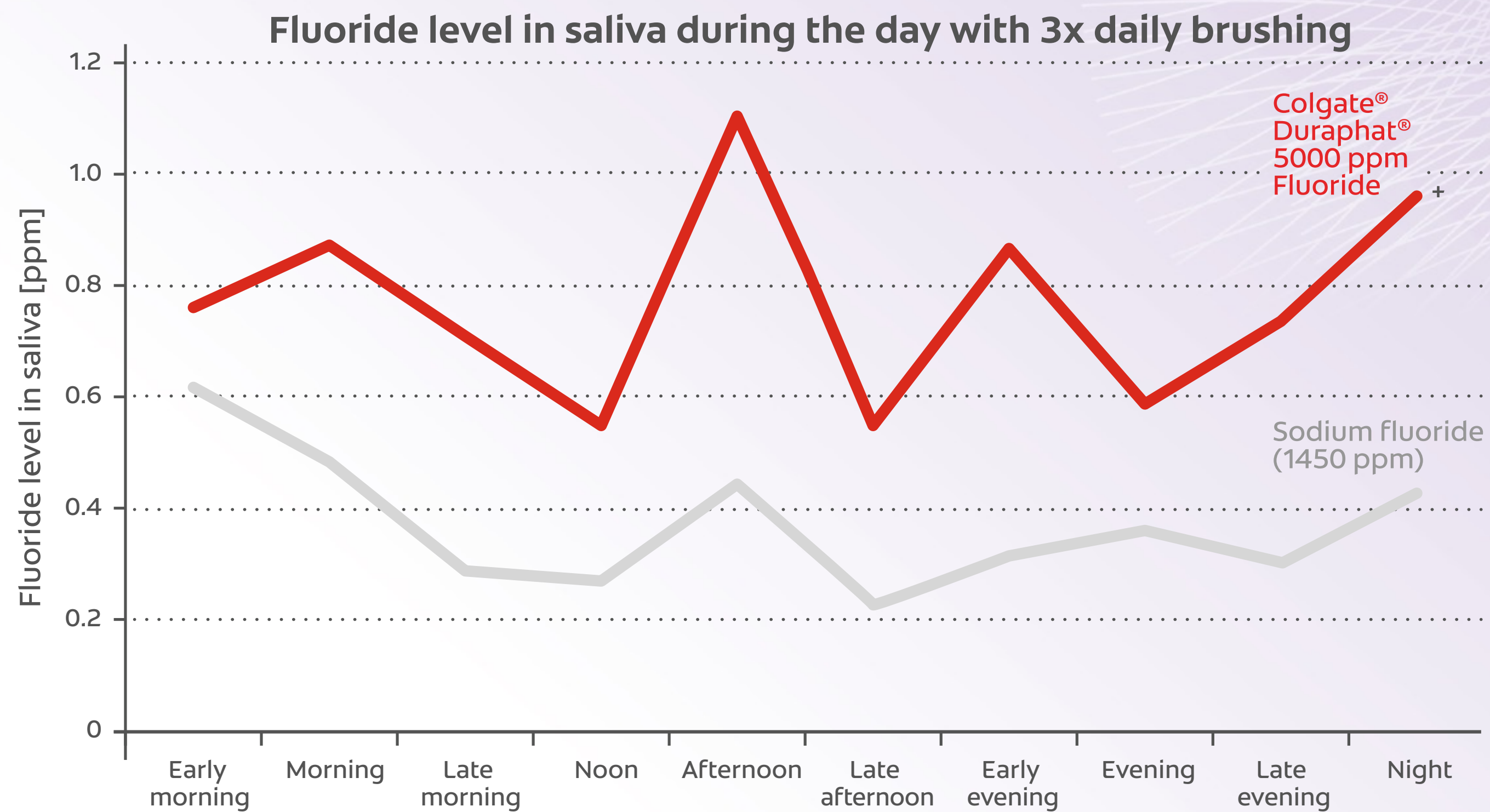


Next slide





# Colgate® Duraphat® 5000 ppm F- Toothpaste enhances the anti-caries effect of saliva for 24 hours<sup>1,\*</sup>



\* vs a regular fluoride toothpaste with 1450 ppm fluoride

+ p<0.001 vs. Sodium fluoride toothpaste

1. Ekstrand et al. Caries Res 2015;49(5):489-498.

## Page notes

This study shows Colgate® Duraphat® 5000 ppm Fluoride Toothpaste increases the level of fluoride in saliva during the day when brushing 3 times a days ( morning, midday and at bedtime).

Fluoride level has been measured 10 times during the day, early morning, morning, midday and at bedtime.



Previous slide

**Slide 22**

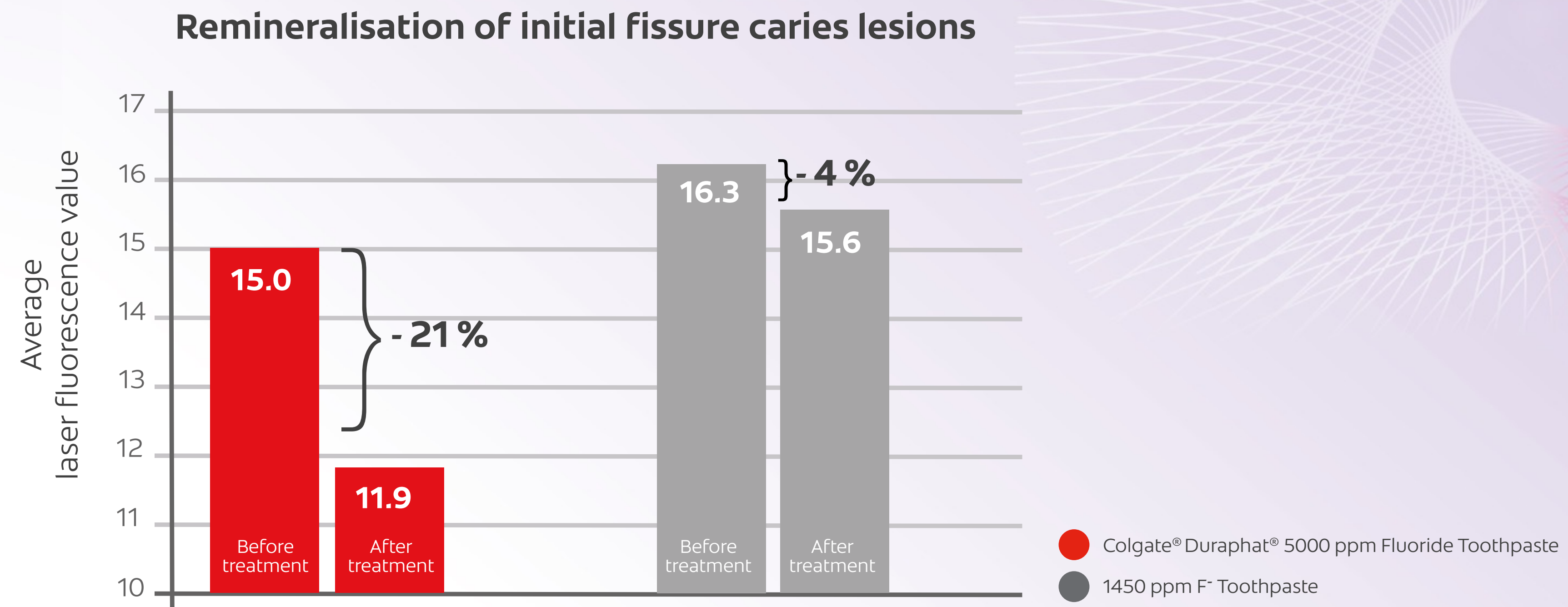


Next slide





# Clinical effectiveness – initial fissure caries lesions



5 times more effective at remineralising initial fissure caries lesions after 14 days

1. Schirmesiter JF et al. Am j Dent 2007;20 212-216

## Page notes

In a clinical trial with 30 patients with early, non-cavitated occlusal lesions, Colgate® Duraphat® 5000 ppm Fluoride Toothpaste was significantly more effective in reducing early fissure caries lesions than a regular 1450 ppm fluoride toothpaste.

The group using 5000 ppm F- toothpaste showed a significantly higher reduction (21 %) in laser fluorescence values, as a measure of caries lesions, compared to the control group (4 %).



Previous slide

**Slide 23**



Next slide



# Clinical studies summary



2800 ppm Sodium Fluoride



22,600 ppm Sodium Fluoride

## Colgate® Duraphat® 2800 ppm Toothpaste

- 20% reduction in DMFS vs a regular fluoride toothpaste containing 1100 ppm<sup>1</sup>

## Colgate® Duraphat® 5000 ppm Toothpaste

- 3x more arrested root caries lesions than 1450 ppm toothpaste after 8 months of use<sup>2</sup>
- remineralises 2x more primary root caries lesions after 6 months vs a regular fluoride toothpaste containing 1100 ppm fluoride<sup>2</sup>
- increases the level of fluoride in saliva during the day when brushing 3 times a day (morning, midday and at bedtime)<sup>4</sup>
- remineralises initial fissure caries lesions significantly more effectively than a 1450 ppm F<sup>-</sup> toothpaste after 14 day use<sup>5</sup>

1. Biesbrock et al. Community Dent Oral Epidemiol 2001;29:382-9. 2. Ekstrand Gerodontology 2008; 25:67-75. 3. Baysan et al. Caries Research 2001;35:41-46. 4. Ekstrand et al. Caries Res 2015;49(5):489-498. 5. Schirrmesiter JF et al. Am J Dent 2007;20 212-216.



## Page notes



Previous slide

**Slide 24**



Next slide





# Prescribing a course of treatment

Prescribe enough Colgate® Duraphat® Fluoride Toothpaste to allow continued use in line with your patients’ next recall interval.

Colgate® Duraphat®	Recall interval		
	1 month**	3 months**	6 months**
2800 ppm F <sup>-</sup>	up to 1 tube	up to 3 tubes	up to 6 tubes
5000 ppm F <sup>-</sup>	up to 1 tube	up to 3 tubes	up to 6 tubes

\* Number of tubes to prescribe aligns with recall interval and usage in line with the product SPC.



## Page notes

Clinical evidence for Colgate® Duraphat® Fluoride Toothpastes supports their continued use to optimise the prevention of caries.<sup>1,2</sup> Consider the date of the patients next recall appointment and prescribe enough tubes to last until then (1 tube lasts approximately 1 month\*\*).

### References:

1. Biesbrock AR et al. Community Dent Oral Epidemiol 2001;29:382-389.
2. Baysan et al. Caries Res 2001; 35(1):41-46.

\* Number of tubes to prescribe aligns with recall interval and usage in line with the product SPC.



Previous slide

Slide 25



Next slide





# Frequently asked questions



**Can I use a Colgate® Duraphat® branded prescription stamp?**

**Yes.** The branded prescription stamp matches the descriptions for Colgate® Duraphat® Fluoride Toothpastes in the Dictionary of Medicine and Devices (dm+d). The dm+d represents all UK medicines and devices.<sup>1</sup>



**If I prescribe a generic, high fluoride toothpaste, am I saving the NHS money?**

**No.** The Drug Tariff Price which is reimbursed to pharmacists is a fixed price, irrespective of the brand/generic high fluoride toothpaste dispensed.<sup>2-4</sup>

## Page notes

References:

1. [www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dictionary-medicines-and-devices-dmd](http://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dictionary-medicines-and-devices-dmd) (last accessed 18.03.2019).
2. [www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff](http://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff) (last accessed 18.03.2019).
3. [www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish-Drug-Tariff/Drugs-and-Preparations-with-Tariff-Prices.asp](http://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish-Drug-Tariff/Drugs-and-Preparations-with-Tariff-Prices.asp) (last accessed 18.03.2019).
4. [www.hscbusiness.hscni.net/services/2034.htm](http://www.hscbusiness.hscni.net/services/2034.htm) (last accessed 18.03.2019).



Previous slide

**Slide 26**



Next slide



# Frequently asked questions - continued



**Can I prescribe multiple tubes on one prescription?**

**Yes.** Dental practitioners work to defined patient care pathways informed by the evidence base, identified disease risk and NICE guidelines on recall intervals.

Dental practitioners may therefore consider prescribing multiple tubes to allow continued patient use until their next recall appointment.<sup>1</sup>



**Which patients should I prescribe Colgate® Duraphat® Fluoride Toothpastes to?**

High fluoride toothpastes are indicated for patients with:<sup>2</sup>

- high caries risk
- active or potential root caries
- orthodontic appliances
- high cariogenic diet
- long term medication/dry mouth
- overdentures

## Page notes

References:

1. Standard General Dental Services Contract July 2018, NHS England.
2. Delivering better oral health: an evidence-based toolkit for prevention, Third Edition, Public Health England, June 2014.





# Colgate® Duraphat® Fluoride Toothpastes

## Benefits for you...

- Provides increased fluoride availability to remineralise primary root caries by 76%<sup>1,\*</sup>
- Available to prescribe from the Dental Practitioners formulary within the British National Formulary (BNF)<sup>2</sup>
- Supports patient compliance

## Benefits for your patients...

- Increased caries prevention vs. regular fluoride toothpaste
- Convenient use – just like a regular toothpaste
- The brand your patients know and trust\*\*
- Mint flavour – to support compliance



## Page notes



Previous slide

**Slide 28**



Next slide





# Colgate® Duraphat® Fluoride Toothpastes

## Directions for use:

- Use instead of a regular fluoride toothpaste
- For 2800 use 1cm and brush 2 times a day
- For 5000 use 2cm and brush 3 times a day
- Spit excess out – do not swallow – avoid rinsing
- Ensure your patients continued use
- Consider prescribing multiple tubes in line with their next recall interval
- After completing the course of treatment, evaluate if the patient needs to continue with high fluoride toothpaste on-going



## Page notes

Colgate® Duraphat® Fluoride Toothpaste should in general be used for min 3-6 months. For some it will be for life time – it depends on the patients' risk factor.



Previous slide

**Slide 29**



Next slide







## Page notes

Thank you for time reviewing this ECPD programme. Please [click here](#) to complete the ECPD survey to gain up to 1-hour ECPD.

**COMPLETE SURVEY**



Previous slide

**Slide 30**



Next slide





# Colgate® Duraphat® 2800 ppm Fluoride Toothpaste – abridged Prescribing Information

**Name of the medicinal product:** Duraphat® 2800 ppm Fluoride Toothpaste. **Active ingredient:** Sodium Fluoride 0.619%w/w (2800 ppm F-). **Indications:** For the prevention and treatment of dental caries (coronal and root) in adults and children over 10 years. **Dosage and administration:** Adults and children over 10 years old: Use daily instead of normal toothpaste. Apply a 1cm line of paste across the head of a toothbrush and brush the teeth thoroughly for one minute morning and evening. Spit out after use; for best results do not drink or rinse for 30 minutes. **Contraindications:** Individuals with known sensitivities should consult their dentist before using. Not to be used in children under 10 years old. **Special warnings and precautions for use:** Not to be swallowed. **Undesirable effects:** When used as recommended there are no side effects. **Legal classification:** POM. **Marketing authorisation number:** PL00049/0039. **Marketing authorisation holder:** Colgate-Palmolive (U.K.) Ltd. Guildford Business Park, Midleton Road, Guildford, Surrey, GU2 8JZ. **Recommended retail price:** £5.10 (75ml tube). **Date of revision of text:** January 2015.



## Page notes



Previous slide

Slide 31



Next slide





# Colgate® Duraphat® 5000 ppm Fluoride Toothpaste – abridged prescribing information

**Name of the medicinal product:** Duraphat 5000® ppm Fluoride Toothpaste. **Active ingredient:** Sodium Fluoride 1.1%w/w (5000ppm F-). 1g of toothpaste contains 5mg fluoride (as sodium fluoride), corresponding to 5000ppm fluoride. **Indications:** For the prevention of dental caries in adolescents and adults over 16 years of age, particularly amongst patients at risk from multiple caries (coronal and/or root caries). **Dosage and administration:** Brush carefully on a daily basis applying a 2cm ribbon onto the toothbrush for each brushing. 3 times daily, after each meal.

**Contraindications:** This medicinal product must not be used in cases of hypersensitivity to the active substance or to any of the excipients. **Special warnings and precautions for use:** An increased number of potential fluoride sources may lead to fluorosis. Before using fluoride medicines such as Duraphat, an assessment of overall fluoride intake (i.e. drinking water, fluoridated salt, other fluoride medicines - tablets, drops, gum or toothpaste) should be done. Fluoride tablets, drops, chewing gum, gels or varnishes and fluoridated water or salt should be avoided during use of Duraphat

Toothpaste. When carrying out overall calculations of the recommended fluoride ion intake, which is 0.05mg/kg per day from all sources, not exceeding 1mg per day, allowance must be made for possible ingestion of toothpaste (each tube of Duraphat 500mg/100g Toothpaste contains 255mg of fluoride ions). This product contains Sodium Benzoate. Sodium Benzoate is a mild irritant to the skin, eyes and mucous membrane. **Undesirable effects:** Gastrointestinal disorders: Frequency not known (cannot be estimated from the available data): Burning oral sensation. Immune system disorders: Rare ( $\geq 1/10,000$  to  $< 1/1,000$ ):

Hypersensitivity reactions. **Legal classification:** POM. **Marketing**

**authorisation number:** PL00049/0050. **Marketing authorisation holder:** Colgate-Palmolive (U.K.) Ltd. Guildford Business Park, Midleton Road, Guildford, Surrey, GU2 8JZ. **Recommended retail price:** £7.99 (51g tube). **Date of revision of text:** February 2015.

## Page notes



Previous slide

Slide 32