

A randomized clinical trial of the anti-caries efficacy of 5000 compared to 1450 ppm fluoridated toothpaste on root caries lesions in elderly disabled nursing home residents

Ekstrand KR, Poulsen JE, Hede B, Twetman S, Qvist V, Ellwood RP: Caries Res. 2013;47(5):391-8



Aim

To evaluate how effective toothbrushing with a 5000 ppm fluoride toothpaste is to control root caries lesions when done by nurses in elderly disabled people living in nursing home versus a control group in which 1450 ppm fluoride toothpaste was used.



Products under investigation

Test product: Duraphat® 5 mg/g fluoride toothpaste containing 5000 ppm fluoride
Positive control product: Colgate® Ultra Cavity Protection containing 1450 ppm fluoride



Study subjects

125 residents of nursing homes (mean age of 81.7 years) in Copenhagen who were no longer able to brush their teeth by themselves completed the study and were included in the final analysis.



Method

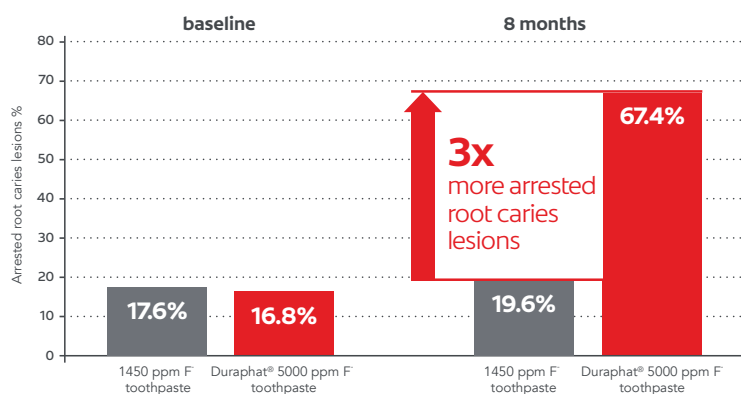
A randomised, parallel clinical study, where subjects in each group had their teeth brushed twice daily by the nursing staff with the allocated toothpaste for an 8 month study period. Subjects were instructed to refrain from using any other fluoride containing oral care products for the duration of the study. Each root caries lesion was examined at baseline and after 8 months.



Results

After 8 months' use, Duraphat® 5 mg/g fluoride toothpaste arrested 67.4% of the root caries lesions, which was 3 times more than a traditional 1450 ppm fluoride toothpaste.

No side effects were noted during the study.



Implications for practice

This study demonstrates that Duraphat® 5 mg/g fluoride toothpaste with 5000 ppm fluoride is significant more effective for controlling root caries lesions progression by arresting 3 times more root caries lesions than a 1450 ppm fluoride toothpaste in a population who received assistance with brushing twice daily in a long-term care setting.

Reversal of primary root caries using dentifrices containing 5000 and 1100 ppm fluoride

Baysan A, Lynch E, Ellwood R, Davies R, Petersson L, Borsboom P: Caries Res. 2001 Jan-Feb;35(1):41-6



Aim

To compare the ability of a high fluoride toothpaste containing 5000 ppm fluoride to a 1100 ppm fluoride toothpaste to remineralise primary root caries lesions.



Products under investigation

Test product: Preident® 5000 Plus toothpaste containing 5000 ppm fluoride

Positive control product: Colgate® Winterfresh gel toothpaste containing 1100 ppm fluoride



Study subjects

186 subjects (mean age of 59 years) with one or more primary root caries lesions completed the study.



Method

A randomised, double-blind, parallel clinical study, where subjects in each group brushed their teeth at least once a day with the allocated toothpaste for the 6 month study period. Subjects were instructed to refrain from using any other fluoride containing oral care products for the duration of the study. Each root caries lesion was examined at baseline, and after 3 and 6 months by a single examiner.

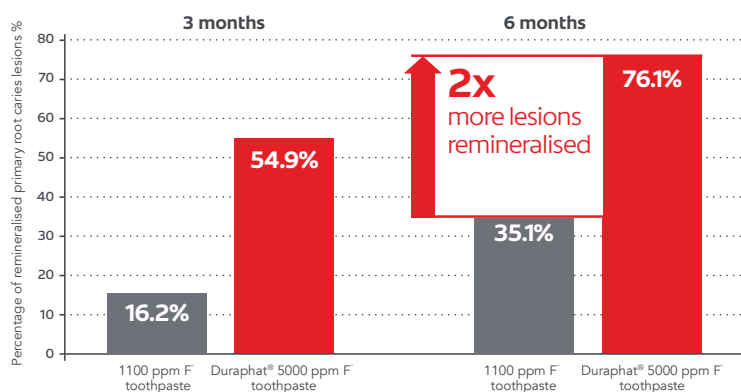


Results

After 3 months' use, the 5000 ppm containing fluoride toothpaste remineralised 54.9% of the root caries lesions compared to 16.2% for those using 1100 ppm fluoride toothpaste.

After 6 months' use, the remineralisation % increased further to 76.1% for the 5000 ppm fluoride toothpaste, which was double the remineralisation % for the 1100 ppm toothpaste.

No side effects were noted during the study.



Implications for practice

This study demonstrates that primary root caries lesions can be treated non-operatively by the use of fluoride toothpaste and a toothpaste containing 5000 ppm fluoride is significantly more effective than a fluoride toothpaste containing 1100 ppm fluoride.

Whole-saliva fluoride levels and saturation indices in people aged 65+ during use of four different toothpaste regimens

Ekstrand KR, Ekstrand ML, Lykkeaa J, Bardow A, Twetman S: Caries Res. 2015;49(5):489-98



Aim

To analyse the fluoride level and mineral saturation in unstimulated whole saliva during four different toothpaste regimens in people aged 65+ living independently at home.



Products under investigation

Test products: TP1: Colgate® Triple Action toothpaste containing 1450 ppm fluoride (NaF)
 TP2: Colgate® Caries Control toothpaste containing 1450 ppm fluoride (MFP)
 TP3: Duraphat® 5000 toothpaste containing 5000 ppm fluoride (NaF)
 TP4: Duraphat® 5000 toothpaste containing 5000 ppm fluoride (NaF) with smearing twice daily

Control product: TP0: Subjects usual toothpaste



Study subjects

27 subjects (mean age of 73.5 years) completed the study.



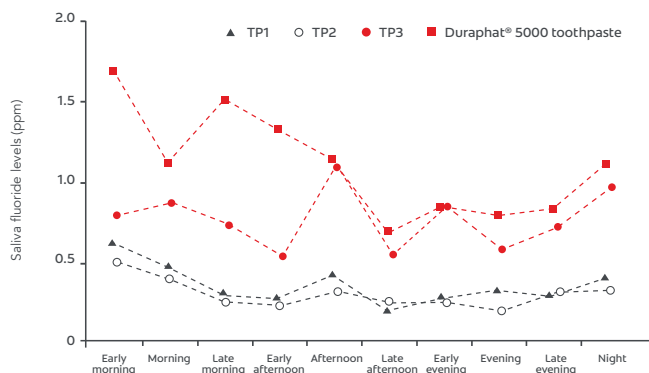
Method

Each subject collected whole saliva at ten time points throughout the day during five 2 week periods. During the first period, subjects used their normal toothpaste without instructions (baseline). This was followed by four subsequent periods using TP1, TP2, TP3 and TP4 where the subjects were instructed to brush 3 times per day using 1.5g of toothpaste without rinsing. Saliva fluoride levels were determined using standard electrodes under ionic strength conditions.



Results

The fluoride level in saliva increased significantly to a higher level using Duraphat® 5000 toothpaste with or w/o smearing 2 times a day compared to the 1450 ppm fluoride toothpastes. The higher fluoride level in saliva was maintained throughout the day.



Implications for practice

This study shows that use of a 5000 ppm fluoride toothpaste results in sustained and persistently elevated fluoride levels in whole saliva throughout the day which may enhance the anti-caries effect of fluoride. This could be relevant in elderly subjects with impaired oral hygiene and subnormal saliva secretion.

Effect of dentifrice containing 5000 ppm fluoride on non-cavitated fissure carious lesions *in vivo* after 2 weeks

Schirrmeyer JF, Gebrande J, Altenburger MJ, Hellwig E: Am J Dent. 2007 Aug;20(4):212-6.



Aim

To compare the ability of a toothpaste containing 5000 ppm fluoride to remineralise non-cavitated fissure caries lesions to a 1450 ppm fluoride toothpaste.



Products under investigation

Test product: Duraphat® 5000 toothpaste containing 5000 ppm fluoride
Positive control product: Colgate® Cavity Protection containing 1450 ppm fluoride



Study subjects

30 subjects with non-cavitated fissure lesions, restricted to enamel in premolars and molars.



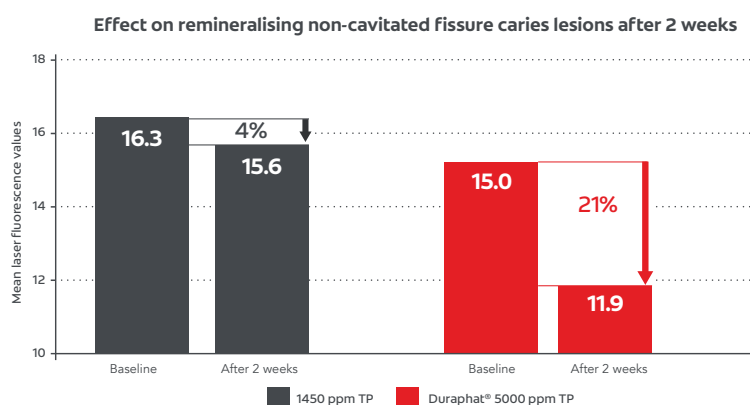
Method

A randomised, single-blind, parallel clinical study, where the subjects were instructed to brush their teeth three times a day for 3 minutes using a 2 cm line of their assigned toothpaste. The subjects were asked to refrain from using any other fluoride products. The lesions were measured at baseline and after two weeks using the DIAGNOdent laser fluorescence device.



Results

Brushing with Duraphat® 5000 toothpaste significantly remineralises non-cavitated fissure caries lesions after 2 weeks' use by decreasing the DIAGNOdent average fluorescence values by 21% compared to a traditional 1450 ppm fluoride toothpaste by 4%. No side effects were noted during the study.



Implications for practice

This study shows that Duraphat® 5000 ppm toothpaste is effective in remineralising non-cavitated enamel fissure caries lesions when used 3 times a day for brushing. This indicates that it is suitable for use by adolescents (16+ years) and adults with high caries risk to prevent fissure caries.

Relative anti-caries efficacy of 1100, 1700, 2200, and 2800 ppm fluoride ion in a sodium fluoride dentifrice over 1 year

Biesbrock AR, Gerlach RW, Bollmer BW, Faller RV, Jacobs SA, Bartizek RD: Community Dent Oral Epidemiol. 2001 Oct;29(5):382-9.



Aim

To examine the anti-caries effectiveness of fluoride compared toothpastes containing 1700 ppm, 2200 ppm and 2800 ppm fluoride to a 1100 ppm fluoride toothpaste.



Products under investigation

Test products

- A. 1700 ppm fluoride toothpaste
- B. 2200 ppm fluoride toothpaste
- C. 2800 ppm fluoride toothpaste

Positive control product: D. 1100 ppm fluoride toothpaste



Study subjects

5,439 children, aged from 6-15 years (mean age of 9.5 years) with tactile and radiographic confirmed enamel lesions completed the study.



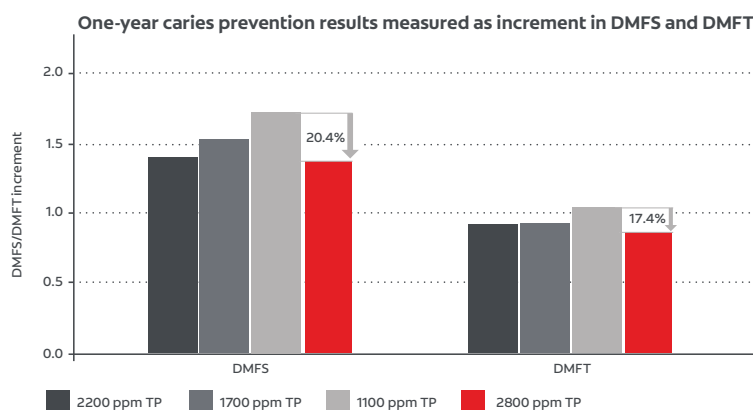
Method

A randomised, double-blind, parallel clinical study, where the children in each group were instructed to use the assigned toothpaste "ad libitum" at home. DMFS and DMFT were scored at baseline and after one year.



Results

The one year results show that the 2800 ppm fluoride toothpaste was most effective in the prevention of caries, as it showed the lowest DMFS and DMFT increment after 1 year of use. It reduced DMFS increment by 20.4% versus a 1100 ppm fluoride toothpaste and 17.4% in DMFT increment.



Implications for practice

This study shows a positive dose response in caries prevention for concentration of fluoride toothpaste ranging from 1100 to 2800ppm. The 2800 ppm toothpaste provided significantly better caries prevention compared to the 1100 ppm toothpaste and may be considered for people over 10 years old with high caries risk.

DK **Duraphat® 5 mg/g fluor som natriumfluorid, tandpasta**

Indikation: Forebyggelse af dental caries hos unge og voksne, specielt hos patienter med risiko for multipel caries (i tandkronen og/eller tandroden). **Dosering og indgivelsesmåde:** Personer over 16 år: 2 cm stribe tandpasta på tandbørsten før hver tandbørstning; tænderne børstes 3 gange dagligt efter hvert måltid, børst lodret fra gumme til tandkant i ca. 3 min. Dental anvendelse. Må ikke synkes. **Kontraindikationer:** Overfølsomhed over for det aktive stof eller over for et eller flere af hjælpestofferne. **Særlige advarsler og forsigtighedsregler:** Må ikke anvendes af børn og unge under 16 år. Anvendelse af flere fluoridkilder kan føre til fluorose. Der skal foretages en overordnet vurdering af det totale fluorindtag for brug. Fluoridtabletter, -dråber, -tyggummi, -geler, -lakker eller fluorideret vand eller salt bør undgås ved samtidig brug af Duraphat tandpasta. Risikoen for at synke noget tandpasta skal tages i betragtning, når beregning af den anbefalede indtagelse af fluorid beregnes. Produktet indeholder natriumbenzoat. Benzoater virker mildt irriterende på hud, øjne og slimhinder. **Graviditet og amning:** Denne tandpasta bør ikke anvendes under graviditet eller amning, med mindre der er foretaget en omhyggelig vurdering af risici og fordele. **Bivirkninger:** Hyppighed ukendt (kan ikke vurderes ud fra tilgængelige data): Brændende fornemmelse i munden. Sjældne ($\geq 1/10.000$ til $< 1/1.000$): Overfølsomhedsreaktioner. **Overdosering:** Den toksiske fluoridosis er 5 mg pr. kg legemsvægt. Symptomer på overdosering: fordøjelsesproblemer: opkastning, diarré, mavesmerter. I ekstremt sjældne tilfælde kan en overdosis være dødelig. Hvis der er indtaget en betydelig mængde af produktet ved en fejltagelse, skal patienten straks have foretaget en maveskylling, eller opkastning skal fremprovokeres; calcium bør indtages (store mængder mælk), og patienten skal holdes under opsyn i flere timer. Duraphat indeholder menthol, som kan forårsage kramper især hos spædbørn og børn, hvis det ved et uheld indtages i store mængder. Tandemaljen vil få et plettet eller spættet udseende, hvis der absorberes mere end 1,5 mg fluor daglig over flere måneder eller år, afhængig af graden af overdosering. Dette vil blive efterfulgt af øget, alvorlig skørhed i emaljen. Knoglefluorose ses kun ved høj, vedvarende absorption af fluor (over 8 mg daglig). **Pakningsstørrelser:** 1 x 51 g tube eller 3 x 51 g tuber. For dagsaktuel pris se www.medicinpriser.dk. **Udlevering og tilskud:** B - ikke tilskudsberettiget. **Andre lægemiddelformer:** Duraphat® findes også som dentaluspension. **Indehaver af markedsføringstilladelsen:** Colgate-Palmolive A/S. **Forkortet i forhold til det af Lægemiddelstyrelsen godkendte produktresumé,** (Opdateret november 2016) der kan rekvireres vedragsfrit fra Colgate-Palmolive A/S, Bredevej 2A, 2830 Virum, telefon: 43 20 92 00.

NO **Duraphat «Colgate Palmolive A/S»
Natriumfluorid**
Kariesprofylaktikum

Reseptgruppe C

ATC-nr.: A01A A01

TANNPASTA 5 mg/g: 1 g inneh.: Fluor 5 mg (som natriumfluorid) tilsv. 5000 ppm fluor, natriumbenzoat (E 211), hjælpestoffer. **Indikationer:** Forebyggelse af dental caries hos ungdom og voksne, særlig blant pasienter som er utsatt for flere typer caries (koronal og/eller rotkaries). **Dosering:** Skal kun brukes av voksne og ungdom >16 år. En 2 cm lang stripe (gir 3-5 mg fluor) påføres tannbørsten for hver tannpass. Tennene pusses grundig 3 ganger daglig, etter hvert måltid, vertikalt, fra tannkjøttet til tannspissen. **Administrering:** Skal ikke svelges. Grundig pusning tar ca. 3 minutter. **Kontraindikasjoner:** Overfølsomhet for noen av innholdsstoffene. **Forsiktighetsregler:** Skal ikke brukes av barn eller ungdom <16 år. Tannpastaen har et høyt fluorinnhold og tannspesialist bør derfor konsulteres før bruk. Et økt antall potensielle fluoridkilder kan føre til fluorose. Før bruk bør det foretas en vurdering av samlet fluorinntak (dvs. drikkevann, salter som inneholder fluor, andre legemidler med fluor som tablett, dråper, tyggummi eller tannpasta). Fluoridtabletter, -dråper, tyggummi, -gel eller -lakk og vann eller salt tilsett fluor, skal unngås ved bruk av Duraphat tannpasta. Ved utregning av anbefalt mengde fluorioner (0,05 mg/kg pr. dag fra alle kilder og maks. 1 mg pr. dag) må mulig svelging av tannpastaen tas med i beregning (hver tube inneholder 255 mg fluorioner). Preparatet inneholder natriumbenzoat som virker mildt irriterende på hud, øyne og slimhinner. **Graviditet/Amning:** Det foreligger ikke tilstrekkelige data fra bruk hos gravide. Dyrestudier har vist reproduksjonstoksiske effekter ved svært høye natriumfluoriddoser. Preparatet skal derfor ikke brukes ved graviditet og amning, med mindre det er utført en grundig nytte-/risikovurdering. **Bivirkninger:** Sjeldne ($> 1/10.000$ til $< 1/1.000$): Immunsensitivitetsreaksjoner. Ukjent: Gastrointestinale: Brennende følelse i munnen. **Overdosering/Forgiftning:** Akutt intoksikasjon: Toksisk dose er 5 mg fluor/kg kroppsvekt. Symptomer: Fluor: Fordøyelsesproblemer som oppkast, diaré og ab-dominalsmerter. I svært sjeldne tilfeller kan det være dødelig. Mentol: Kan forårsake kramper ved inntak av store mengder, spesielt hos småbarn og barn. Behandling: Når en betydelig mengde svelges ved et uheld, må pasienten gjennomgå tarmskylning omgående eller brekninger må fremtvinges. Det må tas kalsium (store mengder melk) og pasienten må holdes under medisinsk observasjon i flere timer. Kronisk intoksikasjon: Fluorose: Tannemaljen vil få et misfarget eller flekkete utseende når en fluordose $> 1,5$ mg/dag absorberes daglig over flere måneder eller år, avhengig av dosestørrelsen. Dette vil ledsages av alvorlige former for økt skjørhet i tannemaljen. Benfluorose (osteosklerose) blir kun observert ved høy kronisk fluorabsorpsjon (> 8 mg daglig). **Pakninger og priser:** 51 g. Dagens pris pr. september 2019: 95,80 NOK. Se www.felleskatalogen.no

SE **Läkemedlets namn:** Duraphat® 5 mg/g tandkräm. 1 g tandkräm innehåller 5 mg fluor (som natriumfluorid), motsvarande 5 000 ppm fluorid. **Indikation:** Förebyggande av dental caries hos ungdomar och vuxna, speciellt hos patienter med risk för multipla kariesangrepp (karies i tandkrona och/eller tandrötter). **Kontraindikationer:** Överkänslighet mot den aktiva substansen eller något av de övriga innehållsämnen. **Varningar och försiktighet:** Ska inte användas av barn och ungdomar under 16 år. Bør endast användas efter samråd med tandläkare på grund av det höga fluorinnehållet. Ett ökat antal möjliga källor för fluor kan leda till fluoros. Innan Duraphat® används, bör en genomgång av det totala intaget av fluorid göras. Fluor i form av tablett, droppar, tyggummi, geler eller tandlack och fluoriderat vatten eller salt ska undvikas under användningen. Vid beräkning av det rekommenderade intaget av fluoridjoner, som är 0,05 mg/kg/dygn från samtliga källor, och som inte bör överstiga 1 mg per dygn, bör hänsyn tas till möjligt intag av tandkräm (en tub Duraphat® tandkräm innehåller 255 mg fluoridjoner). Innehåller natriumbenzoat, som kan verka svagt irriterande på hud, ögon och slemhinnor. **Graviditet och amning:** Ska inte användas under graviditet och amning om inte en noggrann risk/nyttavärdering har gjorts. **Innehavare av godkännande för försäljning:** Colgate-Palmolive A/S, Bredevej 2A 2830 Virum, Danmark. **Receptstatus och förmån:** Receptfritt. Förmånsberättigat. 1 x 51 g tub. **Senaste översyn av produktresumé:** 2016-12-13. För ytterligare information: www.fass.se.

FI **DURAPHAT® 5 mg/g hammastahna**

Vaikuttava aine: 1 g hammastahnaa sisältää natriumfluoridia vastaten 5 mg fluoridia (5 000 ppm). **Käyttöaiheet:** Aikuisten ja nuorten hammaskarieksen ehkäisy etenkin, jos vaarana on useiden hampaiden karies (kruunu- ja/tai juurikaries). **Annostus ja antotapa:** Ainoastaan ≥ 16 -vuotiaiden potilaiden käyttöön. Hampaat harjataan huolellisesti 3 kertaa päivässä, jokaisen aterian jälkeen. Hammasharjalle annostellaan 2 cm hammastahnaa (sisältää 3-5 mg fluoridia) ja hampaat harjataan pystysuorin liikkein harjasta alkaen purupintaa kohti. Huoleellinen hampaiden harjaus kestää noin kolme minuuttia. **Antotapa:** Hammaslääkintään. Ei saa niellä. **Vasta-aiheet:** Yliherkkyyss vaikuttavalle aineelle tai apuaineille. **Varoitukset ja käyttöön liittyvät varoitimet:** Valmistaja ei ole tarkoitettu alle 16-vuotiaille nuorille ja lapsille. Valmisteen fluoripitoisuus on korkea. Useiden eri fluorilähteiden käyttö voi aiheuttaa fluoroosia. Potilaan fluorin kokonaissaanti on arvioitava ennen valmisteen käyttöä. Suositeltava fluoridi-ionien kokonaissaanti kaikista fluorilähteistä on 0,05 mg/kg/vrk, enintään 1 mg/vrk. Valmisteen käytön aikana on vältettävä fluoritabletteja, -tippoja, -purukumia, -geelejä, -lakkoja, fluorattua vettä ja fluorattua suolaa. Valmistaja sisältää natriumbensoattia, joka saattaa lievästi ärsyttää ihoa, silmiä ja limakalvoja. **Yhteisvaikutukset:** Ei tunnetta. **Raskaus ja imetyks:** Valmistetta ei saa käyttää raskauden eikä imetyksen aikana, ellei riskejä ja hyötyjä ole arvioitu huolellisesti. **Haittavaikutukset:** Esiintyvyys tuntematon (saatavissa oleva tieto ei riitä arviointiin): polttelun tunne suussa. Harvinaiset: yliherkkyyssreaktio. **Pakkaukset ja hinnat (vmh + alv 09-2019):** 1 x 51 g tuubi 8,72 € **Korvattavuus:** Ei SV-korvattava. **Reseptilääke.** **Lisätietoja:** Valmistusyhteenveto, Pharmacia Fennica, Colgate-Palmolive A/S, Bredevej 2, DK-2830 Virum, Tanska. **Tutustu valmistusyhteenvetoon ennen lääkkeen määräämistä.** Perustuu 6.10.2016 päivättyyn valmistusyhteenvetoon.

UK **Duraphat 2800ppm**

Colgate® Duraphat® 2800 ppm Fluoride Toothpaste - **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.

Duraphat 5000ppm

Colgate® Duraphat® 5000 ppm Fluoride Toothpaste - **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.