

Title: UK Dental Medicines Advisory Service – Questions asked by dentists: Part 4 – Prescribing of high strength fluoride toothpastes and use of fluoride varnishes in dental practice

Running Title: Questions asked by dentists: Prescribing of high strength fluoride toothpastes and use of fluoride varnishes in dental practice

Author Information:

Brown, PM¹

Fox, K²

Field, EA³

Randall, C⁴

Author Affiliations:

¹Clinical Lecturer in Restorative Dentistry, School of Dentistry, University of Liverpool, Pembroke Place, L3 5PS

²Honorary Senior Clinical Lecturer in Restorative Dentistry, School of Dentistry, University of Liverpool, Pembroke Place, L3 5PS

³Consultant/ Honorary Professor of Oral Medicine, Liverpool University Dental Hospital, Pembroke Place, Liverpool, L3 5PS

⁴Assistant Director, North West Medicines Information Centre, 70 Pembroke Place, Liverpool, L69 3G

Corresponding Author:

Professor E. Anne Field

Consultant in Oral Medicine

Department of Oral Medicine

Liverpool University Dental Hospital

Pembroke Place

Liverpool

L3 5PS

Email: anne.field@liverpoolft.nhs.uk

ABSTRACT

The UK Dental Medicines Advisory Service (UKDMAS) provides advice to dentists and other dental healthcare professionals concerning the use of medicines and medical devices in dental prescribing, administering, or dispensing. The commonly asked questions posed to the UKDMAS concerning the prescribing of high strength, fluoride toothpastes and use of fluoride varnishes in dental practice are discussed with answers, supplemented by relevant information from clinicians.

These include; the prescribing of high strength, fluoride toothpastes and application of fluoride-varnish in particular patient groups, issues concerning the amounts of fluoride toothpaste that can be prescribed, regulations related to the supply of fluoride toothpastes by dental hygienists and therapists and the constituents and selection of fluoride varnishes.

Key Points

The UK Dental Medicines Advisory Service (UKDMAS) provides advice to dentists and other dental healthcare workers on the prescribing of medicines, and the use of medicines and medical devices in dental practice.

Highlights commonly asked questions posed by members of the dental team to the UKDMAS, concerning high strength fluoride toothpastes and fluoride varnishes, providing responses from relevant dental specialities.

Addresses the concerns related to the use of fluoride products in particular patient groups, with respect to prescribing and supplying of high strength fluoride toothpastes and varnishes within the regulatory frameworks.

Introduction

Fluoride is available for dentists to prescribe as a mouth rinse, tablet, high strength (HS) fluoride toothpaste and to buy from dental suppliers as a varnish. All of these formulations supplement a preventative approach, aimed to help reduce caries rates in the adult and child populations in the UK. Fluoride has also been added to local water supplies and primary school milk, in certain areas of the UK to further help reduce caries rates in children. The UK Dental Medicines Advisory Service (UKMDAS) receives many queries from dental practitioners concerning the prescribing of HS fluoride toothpastes and the use of fluoride varnishes. This article includes a selection of these questions and discusses the regulations around prescribing fluoride supplementation, as well as issues relating to the professional application of fluoride varnishes.

Readers are reminded that drug dosages/prescribing/regulations/policies can change, and they should always check up to date resources. For example, the BNF is freely available online (www.BNF.nice.org.uk) and via the app.

Q1. Do High Strength (HS) fluoride toothpastes have any health risks generally or for specific patient groups?

HS fluoride toothpastes are available in two dosages: 2800ppmF (0.619 %) and 5000ppmF (1.1%), and both preparations have a good safety profile, provided they are used at the recommended dosages.

Cautions for the use of HS fluoride toothpastes in patients can be found in their 'Summary of Product Characteristics' (SPC).¹ An SPC can be defined as 'a description of the medicinal products properties and conditions attached to its use.'²

Table 1 shows the topical fluoride content of HS toothpastes at the recommended daily dosages and includes non-prescription, fluoridated toothpastes that are available Over-the-Counter (OTC). The amount of fluoride that could potentially be ingested if the patient intentionally swallows the toothpaste during normal toothbrushing, is also shown.

Table 1- Fluoride content of HS and OTC non –prescription fluoride toothpastes

Fluoride product	Fluoride Content (F)	Recommended age of use (years)	Approx. weight of toothpaste per recommended dosage (g)	Fluoride content per recommended dosage (mg F)	Recommended use (Times/day)	Topical fluoride exposure (mg F/day)
------------------	----------------------	--------------------------------	---	--	-----------------------------	--------------------------------------

Prescription only Medicine (POM) Toothpastes						
Duraphat 5000ppm (51g)	5 mg/g	>16	0.6-1 (2cm ribbon)	3-5	2-3	6-15
Duraphat 2800ppm (75ml)	2.8 mg/g	>10	1 (1cm strip)	2.8	2	5.6

Non –prescription OTC Toothpastes						
1450ppm (75ml)	1.45 mg/g	3-6	0.25 (pea size)	0.36	2	0.72
1450ppm (75ml)	1.45 mg/g	>6	1(1cm strip)	1.45	2	2.9

Asthmatics and those with allergies

There are no specific contraindications for patients with asthma - HS fluoride toothpastes do not contain colophony, which is discussed in Q5 of this article (relates to fluoride varnish).

Renal and hepatic impairment

5000ppm and 2800ppm HS fluoride toothpastes are intended for topical use with minimal systemic exposure.

The SPC, for both HS fluorides indicates no contraindications for use in patients with renal or hepatic impairment.¹

Pregnancy or breast-feeding

Toothpastes with a strength of 2800 ppm fluoride:

The SPC for 2800ppmF 0.619% sodium fluoride toothpaste states that “Epidemiological studies in humans indicate that fluoride has no adverse effects in pregnancy or on the health of the foetus or new born child. Fluoride 2800ppm toothpaste can be used during pregnancy and lactation”.¹ Practitioners should advise

patients, who are pregnant, to pay particular attention to the recommended dosages (toothbrush application) and to avoid swallowing excess amounts of toothpaste.

Toothpastes with a strength of 5000ppm fluoride:

The SPC for 5000ppmF 1.1% sodium fluoride toothpaste contraindicates its use for both pregnancy and lactating women stating that: -

“There is no adequate data from the use of Fluoride 5000 ppm Toothpaste in pregnant women. Studies in animals have shown reproductive toxicity of sodium fluoride only when administered at very high levels. Therefore, this toothpaste should not be used during pregnancy unless careful risk – benefit assessment has been carried out”.

and

“There is no adequate data from the use of Fluoride 5000 ppm Toothpaste in lactating women, and it is unknown if fluoride is excreted in breast milk. Therefore, this toothpaste should not be used during lactation unless careful risk – benefit assessment has been carried out”.¹

If the dentist considers that the benefits of 5000ppm fluoride toothpaste outweigh the potential risks in pregnancy, then prescribing would be ‘off –label’.³

Q2. How many tubes of fluoride toothpaste can I prescribe per prescription?

In 'Delivering Better Oral Health' (DBOH) guidance⁴ examples of prescriptions of HS fluoride toothpastes for both adults and children are offered. These include 3 tubes per prescription but with no recommendation on the duration that these tubes should last. The document also does not offer specific guidance on patient recall intervals for patients using HS fluoride toothpaste. Guidance from FGDP 'Caries Risk Assessment'⁵, NICE guidelines on 'recall intervals between routine examinations'⁶, SDCEP guidance on 'Oral Health Assessment and Review'⁷ and the BNF⁸ informs the calculation of the appropriate number of tubes a practitioner should prescribe to each patient.

HS fluoride toothpastes are indicated for patients who are at a high caries risk, which will in turn determine the appropriate recall interval. Based on an oral health assessment a patient with a high caries risk will usually be offered 3 or 6 monthly recall intervals. Box 1 and Table 2 can be used as a guide to the length of time that the HS toothpastes will last and the number of tubes that need to be prescribed.

The different dosing regimens (toothbrush application) of both 5000ppm and 2800ppm HS toothpastes (Box 1) takes into account the different sizes of the two dispensing lumens (Figure 1)

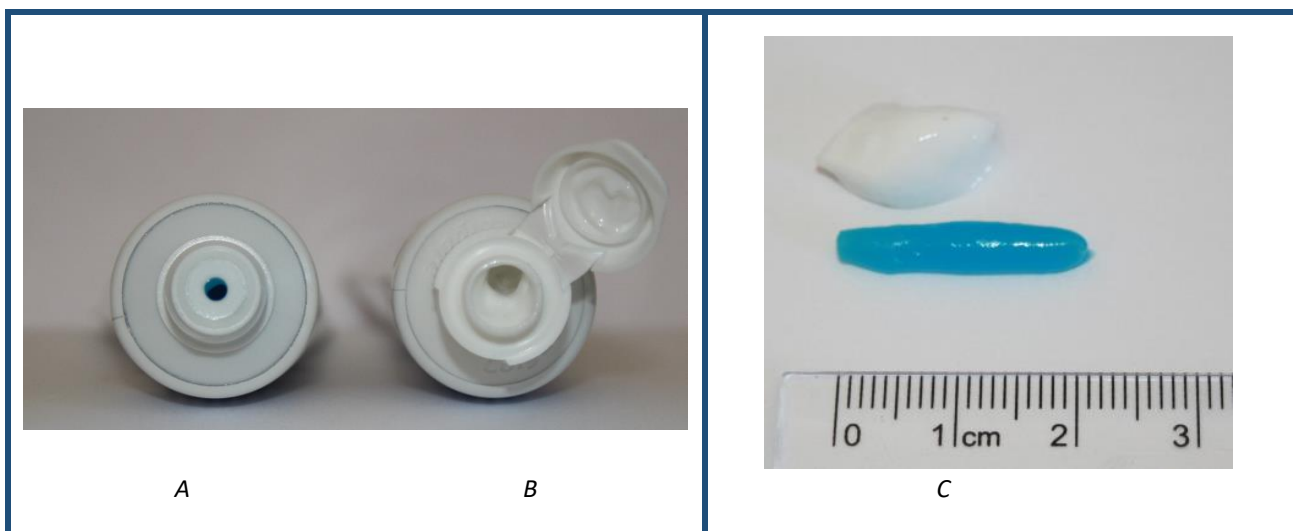
Box 1: Dosing regimens for HS fluoride toothpastes¹

2800ppm Apply 1cm ribbon twice daily (approx. 1g)

5000ppm Apply 2cm ribbon three time daily

(approx. 0.6-1g)

Figure 1 – Photographs illustrating the different diameters of toothpaste tube lumen (A):5000ppm (B) 2800ppm and (C): Ribbons of toothpaste - recommended dosage 5000ppm (blue), 2800ppm (white)



Using the recommended dosages and prescribed number of applications per day as described in the SPC¹ and BNF⁸, appropriately prescribing 5000ppm HS fluoride toothpaste for a patient requires between 3-6 tubes per 3 monthly recall and 6-12 tubes per 6-month recall. However, 2800ppm HS fluoride toothpaste requires prescription of 2-4 tubes for 3 or 6-month recalls respectively (Table 2). Using Table 2 to provide a prescription for the correctly estimated number of tubes will avoid having to re-issue a prescription and avoid the patient paying another prescription charge.

Table 2 – Prescription period (days) fluoride 5000ppm and 2800ppm toothpastes

Toothpaste	Recommended daily dosage	Approx. weight of one application (g)	Approx. number of days toothpaste will last	Number of tubes required every 3/12 recall	Number of tubes required every 6/12 recall
2800ppm (75ml) (weight 100g)	2	1	50	2	4
5000ppm (51g)	3	0.6-1	28-17	3-6	6-12

There are few medicines prescribed by dentists that are used long term apart from HS fluoride toothpaste. A request for additional tubes of HS fluoride toothpaste should be assessed by the dentist. If insufficient amounts have initially been prescribed to last until the next scheduled appointment, an additional prescription can be issued. However, if the patient has not been reviewed for six months or longer the patient should be seen in person. Box 1 and Table 2 can be used to review the patient's use of the prescribed dose and to

understand whether, enough had initially been prescribed, or if the toothpaste is being applied excessively (or misused) by the user.

Q3. What fluoride varnishes are currently available in the UK?

Fluoride varnishes are currently available from dental suppliers in the UK, either as a 'Prescription only Medicine' (POM) or a Medical Device (MD), (see Q4). There are several products available and practitioners should consider the intended use of the varnish for each individual patient, before making a choice (see Table 3). Manufacturers will state the intended use of the varnish on their product labels.

Table 3 – Fluoride varnishes currently available in the UK

Manufacturer	Product name	Fluoride content	Regulatory Status	Product Indications	Notes
Colgate	Duraphat	5% Sodium Fluoride 22,600ppm	POM	<ul style="list-style-type: none"> • Caries prophylaxis • Treatment of hypersensitive teeth • prevention of decalcification around orthodontic appliances 	<ul style="list-style-type: none"> • Contains Colophony • The container of this medicinal product contains latex rubber • Contains alcohol
VOCO	Bifluorid 10	5% Sodium Fluoride 6% Calcium Fluoride 22,600ppm	MD	<ul style="list-style-type: none"> • Treatment of hypersensitive teeth 	<ul style="list-style-type: none"> • Colophony free • Latex safe • Contains alcohol
VOCO	Profluorid	5% Sodium Fluoride 22,600ppm	MD	<ul style="list-style-type: none"> • Treatment of hypersensitive teeth 	<ul style="list-style-type: none"> • Contains Colophony • Latex safe • Contains alcohol
Ivoclar Vivadent	Fluor Protector	0.9% Difluorsilane 1000ppm	MD	<ul style="list-style-type: none"> • Long-term caries prevention • Treatment of hypersensitive teeth 	<ul style="list-style-type: none"> • Colophony free • Latex safe
Ivoclar Vivadent	Fluor Protector S	1.5% Ammonium Fluoride 7700ppm	MD	<ul style="list-style-type: none"> • Caries prophylaxis • Treatment of hypersensitive teeth 	<ul style="list-style-type: none"> • Colophony free • Latex safe • Contains alcohol
SDI	Riva Star	38% Silver Diamine Fluoride 44,800ppm	MD	<ul style="list-style-type: none"> • Treatment of hypersensitive teeth 	<ul style="list-style-type: none"> • Solution can stain.
3M ESPE	Clinpro White Varnish	5% Sodium Fluoride tri-calcium phosphate 22.600ppm	MD	<ul style="list-style-type: none"> • Treatment of hypersensitive teeth 	<ul style="list-style-type: none"> • Latex safe • Contains Colophony • Contains alcohol
Dentsply	NUPRO varnish	5% Sodium Fluoride 22,600ppm	MD	<ul style="list-style-type: none"> • Treatment of hypersensitive teeth 	<ul style="list-style-type: none"> • Gluten safe • Latex safe • Contains Colophony
Henry Schein	HS Fluoride varnish	5% Sodium Fluoride 22,600ppm	MD	<ul style="list-style-type: none"> • Treatment of hypersensitive teeth 	<ul style="list-style-type: none"> • Contains Colophony • Contains alcohol

Q4. Is there a difference between fluoride varnish brands and their use as a “prescribed” product for caries prevention?

Practitioners have multiple options with respect to fluoride varnishes and this could pose some confusion when selecting a varnish that is most appropriate for their patients. Several brands of fluoride varnish are available and are licensed for use in the UK (see table 3) either, as a medicinal product referred to in this article as a prescription only medicine (POM), or registered as a medical device (MD), with a Certification Mark (CE). The marketing of fluoride varnishes as MDs started after 2002 following the introduction of the EU Medical Devices Directive. Prior to that all varnishes were marketed as medicines (Duraphat was licensed in 1995). Today, manufacturers choose to market fluoride varnishes as medical devices as this is more cost-effective than licensing a medicine. A licensed medicine can only be marketed after product testing and clinical trials have taken place, which allows the manufacturer to make evidence-based claims relating to the health benefits of the product for its licensed indications. A MD is granted a CE mark after a conformity assessment by an authorised third party confirms the manufacturer’s legal declaration that the device is safe and performs as intended on the product label. Practitioners should ensure that all products they use, including fluoride varnishes, are either ‘UK licensed medicines’ or ‘registered medical devices’ displaying a CE mark. Table 4 summarises the regulatory classification of each product. Following the Brexit decision in 2019, legislation concerning the regulation of MDs and the use of CE marking will continue to be recognised in Great Britain until 30th June 2023.

Table 4 – Summary of product licence and medical device regulatory classifications

Licence Category	Brief description	Required on product packaging	Legislation that is applied to product	Regulatory Agency
Prescription only Medicine (Medicinal products) (POM)	<i>“Any substance or combination of substances which may be used in, or administered to, human beings, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis”⁹</i>	Product Licence Number (must display ‘POM’)	The Human Medicines Regulations 2012	The Medicines and Healthcare products Regulatory Agency (MHRA) or European Medicines Agency (EMA)
Medical Device (MD)	<i>“The principle mode of action for a medical device is typically fulfilled by physical means (including mechanical action, physical barrier, replacement of, or support to, organs or body functions)”⁹</i>	Certification (registration) Mark (CE)	The Medical Device Directive (MDD)1993 (revised 2007) The Medical Devices Regulation (MDR) 2017	

Overall, it is recommended that dentists using fluoride varnishes for the purpose of caries prevention, carefully consider an individual product’s licence/registration, which should guide the practitioner to the indicated use of the POM or MD (Table 3).

Off - Licence use of fluoride varnishes

Using a fluoride varnish outside the terms of the manufacturer’s stated intentions, has been termed by the Medicines and Healthcare products Regulatory Agency (MHRA) as “off-label” or “off-licence” as discussed in ‘Part 1’ of this series.³

There are several reasons why a practitioner may consider using a fluoride varnish product off-label (Box 2). It is important to discuss the intended benefits of any fluoride product with the patient/parent to ensure that they are fully aware of the intended benefits and risks at each application, which may be “judged by the prescriber to be in the best interests of the patient on the basis of available evidence”.¹⁰ Risks of using an off-label product lie solely with the prescribing practitioner with advice being available on the GOV.UK website¹⁰ and in the Department of Health Toolkit DBOH.⁴

Box 2 – Possible indications for ‘off-label’ use of fluoride varnishes

- Asthmatic patients unable to receive colophony containing products
- Product availability
- Available evidence for the alternative product
- Allergic response to licenced product
- Patients dislike of a product taste preventing its routine use (alternative flavours are available)
- Practitioner experience and use of alternative product, including economic reasons

Q5. Does fluoride varnish have any health risks for specific groups of patients?

Fluoride varnishes, when applied to the surface of teeth, will be absorbed onto the enamel, then slowly release fluoride over 3 weeks.^{11,12}

There are no contraindications to the use of fluoride varnish for patients with medical conditions, other than those with allergies or sensitivities to varnish excipients.

Asthmatics and those with allergies

Colophony, an excipient found in some fluoride varnishes, gives the product a viscosity and stickiness to aid its topical application and adherence to the tooth surface. Sourced from the sap of coniferous trees¹³, it can be found in many personal care products and can induce a reaction in susceptible or atopic individuals and should not be used on patients with asthma. The advice given to clinicians is to avoid applying colophony containing varnishes to those who have a history of allergic episodes requiring hospital admission, including asthma.⁴ This is supported by the 'Prevention and Management of Dental Caries in Children' document¹⁴ and also in the 'Patient Information Leaflet' (PIL) provided for Duraphat 5% sodium fluoride (NaF) varnish.¹ These allergic reactions are typically Type 1 IgE mediated and can have serious consequences such as asthma attacks, anaphylaxis or much milder reactions such as urticaria, oedema and rhinitis.^{15,16,17,18} In view of evidence showing that atopy can be "strongly associated with asthma or wheezy bronchitis"¹⁹, if practitioners feel that an asthmatic patient may benefit from topical fluoride application, it is recommended that a colophony free varnish is given (Table 3).

Duraphat varnish tubes (50mg/ml NaF) have a latex rubber ring, as reported in the special warnings and precautions of the SPC and PIL since Nov 2014, and therefore, its use should be avoided in patients with latex allergies.²⁰

Pregnancy or breast-feeding

The use of fluoride varnishes in pregnant and lactating patients require practitioners to review the product ingredients, which can be found in the PIL or SPC of a POM or in the Material Safety Data Sheet or product leaflet supplied by the manufacturer of a MD. There is minimal risk to the developing foetus if a daily intake of

1mg F were to occur.²¹ Some fluoride varnishes contain alcohol, and therefore, the manufacturer's information should be consulted before use on pregnant and lactating women.

Q6. Can HS fluoride toothpaste be sold or supplied by a hygienist or therapist under a Patient Group

Direction (PGD)?

'Part 1' of this series described PGDs and how they can be used to allow a hygienist or therapist to sell, supply or administer a named medicine for a specific clinical situation.³

Practices must decide whether the use of PGDs by hygienists and therapists provides a benefit to patient care when considering whether to use them to allow supply of HS fluoride toothpaste. They should consider the following:

- In NHS dental practices dentists are the only clinicians with an NHS performer number
- An NHS performer number is needed to open an NHS course of treatment; therefore, the dentist is always seen first.
- Dentists commonly prescribe HS fluoride toothpaste, when indicated, at initial assessment and future recall/review appointments.
- An NHS prescription for multiple tubes of HS fluoride toothpaste attracts only one prescription charge for a 3-6 month supply.
- There is therefore little need for NHS dental practices to use PGDs for the direct sale/supply of HS fluoride toothpastes by a hygienist or therapist.

In private practice, where a therapist or a hygienist is working under direct access²², there may be an advantage for patients and incentive for the practice to introduce PGDs to allow direct sale/supply of HS fluoride toothpastes to patients by a hygienist or therapist. This will save the dentist assessing the patient and either writing a private prescription or issuing the HS toothpaste themselves. Note that the patient will pay a price set/calculated by the practice. HS fluoride toothpastes are available from dental wholesalers, note that as they are classed as a POM purchase orders for them must be signed by a dentist.

Before practising under a PGD, health professionals should ensure that they:

- have undertaken the necessary initial training and continuing professional development
- have been assessed as competent and authorised to practise by the provider organisation
- have signed the appropriate documentation

- are using a copy of the most recent and in date final signed version of the PGD
- have read and understand the context and content of the PGD²³

The use of PGDs for dentists are outlined by the Humans and Medicines regulations 2012 in Part 12 Chapter 3, clauses 230 and 232.²⁴

Q7. Can fluoride varnish be administered by a hygienist or therapist without a Patient Group Direction?

This depends on whether, the fluoride varnish is a POM or MD (Table 3).

If a POM fluoride varnish has been prescribed by the dentist in the patient record as a 'Patient Specific Direction' (PSD)²⁵ it can be administered by a hygienist or therapist without the need for a PGD. See 'Part 1' of this series.³

Hygienists or therapists working by direct access in a dental practice and applying a POM fluoride varnish to their own patients may find a PGD provides more autonomy.

Application of fluoride varnishes that are MDs does not require a PGD as they are not medicines and therefore medicines legislation does not apply. However, it is strongly recommended that, for legal and governance purposes a protocol agreed locally by the employing organisation is used. The organisation has a legal responsibility for the actions of its employees.

Note that medicines legislation allows POM fluoride varnish to be applied by dental care professionals, including dental nurses, under a protocol overseen by a specialist in dental public health.²⁶

Q8. What is the advice regarding HS toothpaste and Fluoride Varnish in areas where there is water fluoridation or fluoridated milk schemes?

Since the introduction of HS fluoride toothpastes and varnishes, GPs have been responsible for discussing with patients the available evidence and the safe use of fluoride products, to prevent toxicity or the unwanted side effects from high levels of fluoride ingestion.²⁷ Several case studies describe fluoride toxicity, but these were all associated with inappropriate use.²⁸

Fluoridated water (1mg/L or 1ppmF):

Water fluoridation schemes aim to achieve 1mg/L or 1ppm of fluoride in the supply as this has been shown to reduce the number ‘Decayed Missing and Filled Teeth’ (DMFT) in children.^{29,30} Currently in the UK there are approximately 6,126,000 people receiving up to 1ppm natural or artificial fluoride in their water supply.³¹

There are no recommended safe levels of fluoride ingestion in the UK but acute ingestion of more than 5mg/kg of fluoride requires medical attention.³² Table 6 shows typical consumption and resultant levels of fluoride ingestion in areas where natural or artificial fluoride in the water supply reaches 1mg/L (1ppmF).^{27,28}

Table 5 – Estimated fluoride intake from water fluoridated to 1mg/L (1ppmF)

Age	Average body weight (kg)	Estimated average consumption of water (L/day)	Estimated fluoride intake from water (mg/kg/day)	Estimated daily fluoride intake (mg/day)
7 months to 4 years	13	0.8	0.062	0.8
5 to 11 years	27	0.9	0.033	0.9
Above 12 years	57	1.3	0.023	1.3
Adults (≥ 18 years)	70	1.5	0.021	1.5

HS fluoride toothpaste:

The SPC for 5000ppm HS indicates:

“An increased number of potential fluoride sources may lead to fluorosis. Before using fluoride medicines such as Sodium Fluoride 5000 ppm toothpaste, an assessment of overall fluoride intake (i.e. drinking water, fluoridated salt, others 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 Sodium Fluoride 5000 ppm Toothpaste".¹

However, the SPC for 2800ppm HS toothpaste indicates:

"This product is not intended to be swallowed and therefore only minimal systemic exposure is expected".¹

GDPs should however advise patients to follow the prescribed daily dose of 2800 ppm HS fluoride toothpaste, and to avoid swallowing any toothpaste products to avoid toxicity or unwanted side effects such as fluorosis.

Fluoride Varnish:

DBOH⁴ advises that 'Fluoride varnish is one of the best options for increasing the availability of topical fluoride, regardless of the level of fluoride in the water supply'.

Fluoridated Milk:

There have been few milk fluoridation schemes in the UK, Wirral 1995, Knowsley 1997³³, and most recently Blackpool 2016.³⁴ In Blackpool, fluoridated milk is being provided to primary school children that have low levels of natural fluoride in the drinking water (<0.2-0.5ppm), and who also suffer from higher than the national average caries rate.³⁴ Primary school children aged between 5-11 years are being provided with fluoride supplemented milk (189ml containing 0.8mg F (4.2ppm)), which would deliver a similar amount of fluoride as in areas where fluoride levels in the water supply are approximately 1ppm (Table 5).

HS fluoride toothpaste:

The most recent DBOH document⁴ offers no guidance for GDP's in relation to the prescription of HS fluoride toothpastes. However, in reality only 10 and 11 year olds would still be drinking fluoridated milk at school and also eligible to be prescribed a HS 2800 ppm fluoride toothpaste. The same advice as given above for patients living in water fluoridated areas (1ppm) should be followed.

Fluoride varnish:

The aim of schemes supplying school children with fluoridated milk is to deliver a similar amount of fluoride as in areas of the UK where the water is fluoridated to 1ppmF. Therefore, as advice in DBOH advocates its use in water fluoridated areas, fluoride varnish is also indicated for use in children receiving fluoridated milk.

Accessing the UKDMAS

The services provides advice via the telephone Monday to Friday 8.30am until 5.00pm and aims to give answers either during the initial call, within a short time or with a longer time scale depending on the question and the urgency.

Phone: (0151) 794 8113

Email: nwmedinfo@nhs.net

SPS Website for dental medicines information: www.sps.nhs.uk/articles/uk-dental-medicines-advice-service-ukdmas/

References:

1. Medicines and Healthcare products Regulatory Agency 'MHRA'. Online information available at <https://products.mhra.gov.uk> (Accessed Sept 2020, A disclaimer needs to be accepted before access can be granted) Key words to access the Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) (Duraphat 5000, Duraphat 2800, Duraphat 50 mg/ml)
2. MHRA, Product information about medicines (Summary of Product Characteristics). Online information available at <https://www.gov.uk/guidance/find-product-information-about-medicines#spcs> (Accessed Sept 2020)
3. Randall C, Finn D, Field EA. Part 1 – Prescribing Regulations and Medicines. Br Dent J. 2020 (Under review)
4. Delivering better oral health: an evidence-based toolkit for prevention. 4th Edition. Public Health England. 2017.
5. Appendix 5 Caries Risk Assessment Guide. Faculty of General Dental Practice. Online information available at www.fgdp.org.uk/clinical-examination-record-keeping-standards/appendix-5-caries-risk-assessment-guide (Accessed Sept 2020)
6. Dental Checks: intervals between oral health reviews. National Institute for Health and Care Excellence. 2004. Online information available at www.Nice.org.uk/guidance/cg19 (Accessed Sept 2020)
7. Oral Health Assessment and Review. Scottish Dental Clinical Effectiveness Programme. 2011. Online information available at www.sdcep.org.uk/published-guidance/oral-health-assessment (Accessed Sept 2020)
8. Sodium Fluoride: indications and dose. British National Formulary. National Institute Health and Care Excellence. Online information available at <https://bnf.nice.org.uk/drug/sodium-fluoride.html> (Accessed Sept 2020)
9. A guide to what is a medicinal product: MHRA Document. Online information available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/872742/GN8_FINAL_10_03_2020_combined_.pdf (Accessed Sept 2020)
10. GOV.UK. Dec 2014. Online information available at www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities (Accessed Sept 2020)

11. Marinho V C C, Worthington H V, Walsh T et al. Fluoride varnishes for preventing dental caries in children and adolescents (Review). Cochrane Database of Systematic Reviews 2013; 7. Art. No.: CD002279.
12. Shen C, Autio-Gold J. Assessing fluoride concentration uniformity and fluoride release from three varnishes. JADA 2002; 133: 176-182.
13. Downs A M R, Sansom J E. Colophony: a review. Contact Dermatitis 1999; 41: 305-310.
14. SDCEP. Prevention and Management of Dental Caries in Children. Dental Clinical Science. Scottish Dental Clinical Effectiveness Programme. 2010. Available at <https://www.sdcep.org.uk/published-guidance/caries-in-children/> (accessed November 2021).
15. Sharma P R. Allergic Contact Stomatitis from Colophony. Dent Update 2006; 33: 440-442.
16. Isaksson M, Bruze M, Niklasson B. Contact allergy to Duraphat. Scand J Dent Res 1993; 101: 49-51.
17. Scully C. Medical Problems in Dentistry. Other Systems Medicine; Allergies. 6th ed. pp 411- 414. Elsevier. 2010
18. Kumar P J, Clark M L. Kumar and Clarks clinical Medicine. Respiratory disease; Asthma. 6th ed. pp 912-922. Elsevier. 2005
19. Anderson H R, Pottier A C, Strachan D P. Asthma from birth to age 23: incidence and relation to prior and concurrent atopic disease. Thorax 1992; 47: 537-542.
20. Colgate-Palmolive Company. June 2015. Online information available at https://www.colgateprofessional.co.uk/content/dam/cp-sites/oral-care/professional/en-uk/article-pdf/brochure/duraphat_dental_suspension_pdf_july_2015.pdf (Accessed Sept 2020)
21. Schaefer C, Peters P, Miller R K. Drugs During Pregnancy and Lactation. Treatment options and risk assessment. Peters P, Schaefer C. Vitamins, minerals and trace elements. 2nd ed. pp 479. London: Academic Press, 2007.
22. General Dental Council; Standards and guidance. Direct access. Online information available at <https://www.gdc-uk.org/information-standards-guidance/standards-and-guidance/direct-access> (Accessed Sept 2020)
23. NICE: Patient group directions. Medicines practice guideline. 2nd August 2013. Online information available at <https://www.nice.org.uk/guidance/mpg2/chapter/Recommendations> (Accessed Sept 2020)
24. The Human Medicines Regulations 2012. Chapter 3 Exemptions. Online information available at <http://www.legislation.gov.uk/uksi/2012/1916/contents> (Accessed Sept 2020)

25. Specialist Pharmacy Service. Questions about Patient Specific Directions (PSD). Online information available at <https://www.sps.nhs.uk/articles/patient-specific-directions-ga/> (Accessed Sept 2020)
26. Avoidance of Doubt – Application of Fluoride Varnish by Dental Nurses. Online information available at <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/09/avoidance-doubt-v4-1.pdf> (Accessed Sept 2020)
27. Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (Sept 2003). Statement on the 1997 Total Diet Study – Fluorine, Bromine and Iodine. COT Statement 2003/03. Online information available at <https://cot.food.gov.uk/sites/default/files/cot/fluoride.pdf> (Accessed Sept 2020)
28. Fluoride toothpaste – What are the dangers of chronic ingestion in adults? National Clinical Institute for Health and Care Excellence. Online information available at <https://www.sps.nhs.uk/articles/fluoride-toothpaste-what-are-the-dangers-of-chronic-ingestion-in-adults/> (Accessed Sept 2020)
29. Ihezor-Ejiofor Z, Worthington H V, Walsh T et al. Water fluoridation for the prevention of dental caries (Review). Cochrane Database of Systematic Reviews 2015; 6. Art. No.: CD010856.
30. Improving oral health: a community water fluoridation toolkit for local authorities. Public Health England. 2016. Online information available at <https://www.gov.uk/government/publications/improving-oral-health-community-water-fluoridation-toolkit> (Accessed Sept 2020)
31. The British Fluoridation Society. Online information available at <https://bfsweb.org/extent/> (Accessed Sept 2020)
32. Toxbase.org. Online information available at www.toxbase.org (Accessed Sept 2020)
33. Bánóczy J, Petersen P E, Rugg-Gunn A J. Milk fluoridation for the prevention of dental caries. World Health Organisation. 2009.
34. Joint Strategic Needs Assessment Blackpool. Online information available at <http://www.blackpooljsna.org.uk/Developing-Well/Children-and-young-peoples-health/Dental-Health.aspx> (Accessed Sept 2020)