NHS Grampian NHS Highland

Patient Group Direction For The Supply/Administration Of Medicines As Included In The Dental Formulary By Approved Healthcare Professionals Working Within NHS Grampian And NHS Highland

Lead Author: Clinical Dental Director, NHS Highland **Coordinator:** Associate Director of Pharmacy (NHS Highland HSCP)	**Consultation Group:** See relevant page in the PGD	**Approver:** NHSG Medicines Guidelines and Policies Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/DentalF/ MGPG1274	**Review Date:** June 2024 **Expiry Date:** June 2025	**Date Approved:** June 2022

NHS Grampian and NHS Highland have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	Supersedes NHSG/PGD/DentalF/MGPG986 Version 1.1	
Date of change	**Summary of Changes**	**Section heading**
December 2021	Review of PGD.	
May 2022	All staff to have undertaken PGD module training on TURAS Learn	Pg 4 Characteristics of staff authorised to supply/administer medicine(s) under PGD
May 2022	Advisory added to monographs that individuals with any precautions/special warnings should be discussed with a dentist prior to treatment	All product monographs except Sodium Fluoride Dental Suspension 50mg/mL (Duraphat® Dental Suspension) (Administer) and Sodium Fluoride Toothpaste 0.619% w/w (Duraphat® 2800ppm) (Supply)
May 2022	• Children under 4 years of age or under 20kg of body weight excluded from treatment. • Individuals with epilepsy not controlled by treatment added as an exclusion. • Cardiovascular diseases (e.g. heart failure, coronary heart disease, history of myocardial infarction, cardiac arrhythmia, hypertension), cerebral circulation disturbances and history of stroke added as precautions/special warnings • Doses and maximum doses undated as per SmPC	Pg 11- 14 Articaine Hydrochloride 4% And Adrenaline (Epinephrine) 1:200,000 (Septanest® 1:200,000) 2.2mL Cartridges Solution for Injection (Administer)
May 2022	• Bradycardia, acute intermittent porphyria and pheochromocytoma added as exclusion criteria. • Additional precautions/special warnings included. • Doses and maximum doses undated as per SmPC	Pg 15 – 18 Lidocaine Hydrochloride 2% And Adrenaline (Epinephrine) 1:80,000 (Lignospan® Special – latex free) 2.2mL Cartridges Solution for Injection (Administer)

May 2022	• Doses and maximum doses undated as per SmPC	Pg 19 – 21 Mepivacaine Hydrochloride 3% (Scandonest® 3% Plain) 2.2mL Cartridges Solution for Injection (Administer)
May 2022	• Doses and maximum doses undated as per SmPC	Pg 25 – 27 Prilocaine Hydrochloride 30mg/mL With Felypressin 0.54 micrograms/mL (Citanest 3% With Octapressin® 0.066units/2.2mL) 2.2ml Cartridges Solution for Injection (Administer)
May 2022	• Hypersensitivity to colophony added as exclusion to treatment.	Pg 28 – 30 Sodium Fluoride Dental Suspension 50mg/mL (Duraphat® Dental Suspension) (Administer)

NHSG Identifier: NHSG/PGD/DentalF/MGPG1274
Keyword(s): PGD Patient Group Direction therapist hygienist articaine hydrochloride epinephrine septanest duraphat fluoride toothpaste lidocaine hydrochloride adrenaline lignospan mepivacaine scandonest oraqix® prilocaine periodontal felypressin citanest octapressin dental suspension.

Policy Statement: It is the responsibility of individual approved healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:
Drafted: December 2021
Completed: May 2022
Approved: June 2022 (Published August 2022)
Amended & reauthorised:

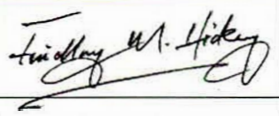
Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Dentist	**Name:** Alexandra Lowe **Health Board:** NHSG **Title:** Dental Clinical Lead NHSG **Contact email:** alexandra.lowe@nhs.scot **Signature** ..... **Date Signed:** 20/07/2022
Senior representative of the professional group who will provide care under the direction.	**Name:** Siobhan Coffield **Health Board:** NHSG **Title:** Dental Therapist/Hygienist **Contact email:** siobhan.coffield@nhs.scot **Signature** ..... **Date Signed:** 16/08/2022
Senior representative of the professional group who will provide care under the direction.	**Name:** Leanne Hamilton **Health Board:** NHSG **Title:** Dental Therapist (Moray) **Contact email:** leanne.hamilton3@nhs.scot **Signature** ..... **Date Signed:** 22/07/2022
Lead Author (if different from above)	**Name:** Rhona Brown **Health Board:** NHSH **Title :** Assistant Clinical Dental Director NHSH **Contact email:** rhona.brown3@nhs.scot **Signature** ..... **Date Signed:** 19/07/2022
Pharmacist	**Name:** Thomas Ross **Health Board:** NHSH **Title:** Associate Director of Pharmacy (Highland HSCP) **Contact email:** Thomas.ross2@nhs.scot **Signature** ..... **Date Signed:** 19/07/2022

Approved and authorised for use within NHSG and NHSH by;

Board PGD or Authorised Subgroup	Chair /Professional Secretary Name	Signature	Date Signed
NHS Highland PGD Subgroup	Findlay Hickey		24/08/2022
NHS Grampian Medicines Guidelines and Policies Group	Lesley Coyle		23/06/2022

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Rhona Brown	**Lead Author:** Assistant Clinical Dental Director, NHSH
Thomas Ross	**Pharmacist:** Associate Director of Pharmacy (Highland HSCP), NHSH
Leanne Hamilton	**Signatory for the Staff Group:** Dental Therapist (Moray) NHSG
Siobhan Coffield	**Signatory for the Staff Group:** Dental Hygienist, NHSG
Alexandra Lowe	**Dentist:** Dental Clinical Lead for Aberdeen City NHSG
Frances Adamson	Medicines Management Specialist Nurse, NHSG

Patient Group Direction For The Supply/Administration Of Medicines As Included In The Dental Formulary By Approved Healthcare Professionals Working Within NHS Grampian And NHS Highland

Clinical indication to which this PGD applies

Definition of situation/ Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to supply or administer medicines, included in the Dental Formulary (Appendix 3) to individuals attending a dental service clinic or during a professional domiciliary visit. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Individuals attending a public dental service clinic or being visited by a dental professional on a domiciliary basis due to their medical condition. The medicines included in this PGD may only be used for the conditions specified within the individual product monograph recommendations and contraindications. Prior to the supply/administration of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	• No medicine in this PGD should be used without consideration of the possible consequences to the individual as detailed in the medicines monographs. • Medicines should not be supplied/administered if the individual has previously had an adverse reaction to the medicine or any of its excipients, is already receiving treatment for the condition or if a contraindication to the supply/administration is specified in the monograph. In these instances the individual should be referred to the dentist. • Where there is no valid consent.
Precautions and special warnings	The medicines listed in this PGD should only be used for the specific conditions detailed in the monographs.

Action if excluded from treatment	If an individual is excluded from treatment under this PGD, document the reason and action taken in the appropriate clinical record. Advice should be sought – refer to the supervising dentist.
Action if treatment is declined	Inform/refer to the relevant dental practitioner if individual/person with parental responsibility declines treatment. Document that the supply/administration was declined, advice given and, if possible and the reason in appropriate clinical records.

Description of treatment available under the PGD

Name form and strength of medicine	See individual medicine monographs.
Legal status	Medicines referred to in this PGD are all either GSL (General Sales List), P (Pharmacy only) or POM (Prescription-only Medicines) dependant on individual medicine and pack size. In accordance with the MHRA all medicines **supplied** under a PGD **must** either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply. Labels must be written for each supply of a medicine under this PGD and must include the following: • Individual's name • The date the medicine is dispensed • The initials of the professional making the supply • The dose to be taken, how to take it and how often.
Dosage/Maximum total dose	See individual medicine monographs.
Frequency of dose/Duration of treatment	See individual medicine monographs.
Maximum or minimum treatment period	N/A
Route/Method of administration	See individual medicine monographs.

Quantity to be supplied/ administered	See individual medicine monographs.
Storage requirements	See individual medicine monographs.
Follow-up (if applicable)	Individuals should not leave the clinic or be left at home alone if they are feeling at all unwell. If necessary a dentist, doctor or the individual's GP should be contacted for advice.
Advice (Verbal)	Advise individual/person with parental responsibility what to expect and what to do for minor and major reactions. If serious adverse or persistent effects occur, the individual/ person with parental responsibility should be advised to contact their GP/Accident and Emergency department/NHS24.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual/person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.
Identifying and managing possible adverse reactions	See individual medicine monographs. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System. Yellow Card Scheme - MHRA

Facilities and supplies required	The following are to be available at sites where the medicine is to be supplied/administered: • Appropriate storage facilities or pharmaceutical refrigerator • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this current PGD in print or electronically.

Characteristics of staff authorised to supply/administer medicine(s) under PGD

Professional qualifications	Dental therapists and dental hygienists registered with the General Dental Council.
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's/person with parental responsibilities capacity to understand the nature and purpose of the medicine supply/administration in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD. • Competent to undertake supply/administration of the medicine • Competent to work under this PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken NoS PGD module training on TURAS Learn • Have attended basic life support training either face to face or online and updated in-line with Board requirements • Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis in-line with Board requirements

	• Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct • Have knowledge and familiarity of the following; ○ SmPC for the medicine(s) to be supplied/administered in accordance with this PGD.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to supply/administer the medicine(s) specified in this direction.

Documentation

Authorisation of supply/ administration	Dental therapists and dental hygienists working within NHS Grampian and NHS Highland can be authorised to supply/administer the medicine specified in this PGD by their Dental Manager. All authorised staff are required to read the PGD and sign the Agreement to Supply and/or Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.
Record of supply/ administration	An electronic or paper record for recording the screening of individuals and the subsequent supply/administration or not of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum: • Date and time of supply/administration • Individual's name and CHI • Exclusion criteria, record why the medicine was not supplied/administered (if applicable) • Record that valid consent to treatment under this PGD was obtained

<table>
<tr><td></td><td>

The name, dose, form, route (batch number, expiry date and site where appropriate for injectable medicines) of the medicine administered/supplied
Advice given, including advice given if excluded or declined treatment under this PGD
Signature and name in capital letters of the healthcare professional who supplied/administered the medicine
Record of any adverse effects (advise individual's GP/relevant medical practitioner).

Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate:

Individual service specific systems.

</td></tr>
<tr><td>Audit</td><td>All records of the medicine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines supplied/administered under a PGD.</td></tr>
<tr><td>References</td><td>Medicines and Healthcare Products Regulatory Agency (MHRA) http://www.mhra.gov.uk/spc-pil/
<table>
<tr><th>Medicine</th><th>Date of Revision of Text</th><th>Date Accessed</th></tr>
<tr><td>Septanest® 1:200,000 2.2ml Cartridges</td><td>31/12/2020</td><td>28/06/2022</td></tr>
<tr><td>Duraphat® 2800ppm Fluoride Toothpaste</td><td>20/01/2015</td><td>28/06/2022</td></tr>
<tr><td>Duraphat Dental Suspension 50mg/ml</td><td>29/11/2019</td><td>28/06/2022</td></tr>
<tr><td>Lignospan Special® 2%</td><td>26/07/2018</td><td>28/06/2022</td></tr>
<tr><td>Scandonest® 3% Plain</td><td>27/03/2020</td><td>28/06/2022</td></tr>
<tr><td>Oraqix® 25/25mg per gram</td><td>15/09/2016</td><td>28/06/2022</td></tr>
<tr><td>Citanest 3% with Octapressin®</td><td>14/09/2016</td><td>28/06/2022</td></tr>
</table>
British National Formulary and British National Formulary for Children accessed 03/12/21.</td></tr>
</table>

Appendix 1

Healthcare Professional Agreement to Supply/Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply/administer the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Supply/Administration Of Medicines As Included In The Dental Formulary By Approved Healthcare Professionals Working Within NHS Grampian And NHS Highland

I have completed the appropriate training to my professional standards enabling me to supply/administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

Appendix 2

Healthcare Professionals Authorisation to Supply/Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to supply/administer the medicine(s) under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to supply/administer the medicine(s) under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply/administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.
Patient Group Direction For The Supply/Administration Of Medicines As Included In The Dental Formulary By Approved Healthcare Professionals Working Within NHS Grampian And NHS Highland
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Supply/Administration Of Medicines As Included In The Dental Formulary By Approved Healthcare Professionals Working Within NHS Grampian And NHS Highland					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

Appendix 3

Dental Formulary

Medicine Monographs

Articaine Hydrochloride 4% And Adrenaline (Epinephrine) 1:200,000 (Septanest® 1:200,000) 2.2mL Cartridges Solution for Injection (Administer) 11

Lidocaine Hydrochloride 2% And Adrenaline (Epinephrine) 1:80,000 (Lignospan® Special – latex free) 2.2mL Cartridges Solution for Injection (Administer) 15

Mepivacaine Hydrochloride 3% (Scandonest® 3% Plain) 2.2mL Cartridges Solution for Injection (Administer) 19

Lidocaine 2.5% And Prilocaine 2.5% (Oraqix®) 1.7g Cartridges Periodontal Gel (Administer) 22

Prilocaine Hydrochloride 30mg/mL With Felypressin 0.54 micrograms/mL (Citanest 3% With Octapressin® 0.066units/2.2mL) 2.2ml Cartridges Solution for Injection (Administer) 25

Sodium Fluoride Dental Suspension 50mg/mL (Duraphat® Varnish) (Administer) ... 28

Sodium Fluoride Toothpaste 0.619% W/V (Duraphat® 2800ppm) (Supply) 31

The information in these monographs is not exhaustive. They must be read in conjunction with the current issue of the British National Formulary and the Summary of Product Characteristics for each medicine.

Articaine Hydrochloride 4% And Adrenaline (Epinephrine) 1:200,000 (Septanest® 1:200,000) 2.2mL Cartridges Solution for Injection (Administer)	
Indication	Local anaesthetic for restorative or periodontal treatment of permanent or deciduous teeth, or where extraction of a deciduous tooth is indicated. **N.B.** Articaine and adrenaline should **not** be used as first choice anaesthetic for any indication. It should only be used where Lignospan Special®, Scandonest® or Citanest 3% with Octapressin® are contraindicated.
Inclusion criteria	• All individuals referred to the dental therapist/hygienist for routine dental treatment within the remit of the dental therapist/hygienist under General Dental Council (GDC) Scope of Practice guidance • Adults and children aged 4 years and over (or from 20kg of body weight) • Valid consent obtained.
Exclusion criteria	• Children under 4 years of age (or under 20kg of body weight) • Pregnancy • Hypersensitivity to any component of the product, in particular individuals who have experienced bronchospasm after administration of products containing sulphites • Individuals not requiring or refusing anaesthesia • Any individual where the medical history is for any reason incomplete or unavailable • Any individual where the maximum dosage of local anaesthesia has been given but anaesthesia remains inadequate • Individuals with epilepsy not controlled by treatment • Individuals with severe hypertension or unstable cardiac rhythm, the use of adrenaline with a local anaesthetic may be hazardous and an anaesthetic without adrenaline should be used • Individuals currently taking or taken in the past two weeks Monoamine Oxidase Inhibitors (MAOI), tricyclic antidepressants, serotonin/noradrenaline reuptake inhibitors antidepressants or phenothiazines • Individuals receiving beta blockers as concurrent use can cause bradycardia and hypotension • Advanced liver disease • Severe renal dysfunction • Infection or inflammation in the region of the proposed injection

Articaine Hydrochloride 4% And Adrenaline (Epinephrine) 1:200,000 (Septanest® 1:200,000) 2.2mL Cartridges Solution for Injection (Administer)	
	• Individuals who require a nerve block (Septanest® is not recommended for nerve block injection).
Precautions and special warnings	**N.B.** Must **not** be given by Intra-vascular injection or used for nerve blocks. Individuals with any of the following precautions/special warnings should be discussed with a dentist prior to treatment: • Hepatic impairment – risk of development of higher plasma concentrations • Renal impairment – use with caution in severe renal impairment • Diabetes, epilepsy, thyrotoxicosis – due to adrenaline containing product • Cardiovascular diseases (e.g. heart failure, coronary heart disease, history of myocardial infarction, cardiac arrhythmia, hypertension) • Cerebral circulation disturbances, history of stroke – recommend defer dental treatment with articane/adrenaline for six months following a stroke due to increased risk of stroke. • Breastfeeding – it is not usually necessary to suspend breastfeeding for short term use, starting from five hours following anaesthesia. The dosage of anaesthetic should be reduced in individuals that are using sedatives, e.g. to reduce apprehension. Refer to BNF and SmPC for complete list. **N.B.** Healthcare professionals should not administer under this PGD if they feel that it is inappropriate for the individual or there are any contraindications for the medicine, refer to dentist.
Legal status	Articaine Hydrochloride 4% And Adrenaline (Epinephrine) 1:200,000 (Septanest® 1:200,000) is a Prescription-only Medicine (POM).
Dose/Maximum total dose	**N.B.** The doses outlined below are a guide as to the quantities of local anaesthetic to be administered. However, care should be taken to ensure treatment of individuals is based on weight and overall medical health, and not just the individual's age.

Articaine Hydrochloride 4% And Adrenaline (Epinephrine) 1:200,000 (Septanest® 1:200,000) 2.2mL Cartridges Solution for Injection (Administer)	
	The lowest dose leading to effective anaesthesia should be used. **Adults and adolescents (12 to 18 years of age):** 2.2mL (a full single cartridge) is generally sufficient for adults - two cartridges can be used in the case of large interventions. **Maximum total dose** - 4.4mL (2 cartridges) per appointment for an adolescent or adult individual. **Children (4 to 11 years of age):** Recommended dose at 0.06mL/kg, e.g. 20kg child - 1.2mL 40kg child - 2.2mL **Maximum total dose** - 3.3mL (One and half cartridges) per appointment for children under 12 years of age.
Frequency of dose/Duration of treatment	If anaesthesia is not adequate, a further dose of the same or alternative anaesthetic solution or an alternative route may be used up to the total dose/number of cartridges stated as per the Dosage/Maximum total dose section above.
Maximum or minimum treatment period	N/A
Route/Method of administration	By sub-mucosal infiltration. To be injected slowly with appropriate precautions to ensure it is not injected directly into a blood vessel. Part used cartridges **must** be discarded as they are not for multiple use.
Quantity to be administered	See Dosage/Maximum total Dose section above.
Potential adverse reactions	Articaine (Septanest®) contains sulphites that may cause hypersensitivity and bronchospasm. **Central nervous system symptoms:** nervousness, shaking, yawning, trembling, apprehension, nystagmus, headache, nausea, buzzing in the ears. **Respiratory symptoms:** tachypnoea, then bradypnoea which can lead to apnoea.

Articaine Hydrochloride 4% And Adrenaline (Epinephrine) 1:200,000 (Septanest® 1:200,000) 2.2mL Cartridges Solution for Injection (Administer)	
	Cardiovascular signs: bradycardia and hypotension Refer to BNF and SmPC for complete list.
Advice (Verbal/written)	• Temporary loss of feeling - numbness for possibly up to 3 - 4 hours. • Post-operative care - advise individual to avoid hot drinks, smoking or chewing hard foods till return of full sensation. Make individual aware of risk to lip or cheek of biting at any time during this period of numbness Advise individuals that if they experience side effects, including dizziness or blurred vision, not to drive or operate machinery until the effects have disappeared.
Monitoring (if applicable)	Monitor for adverse reactions for approximately 15 minutes.
Storage	Store up to 25°C. Store in the original container protected from light. Do not freeze.

Dental Formulary

Lidocaine Hydrochloride 2% And Adrenaline (Epinephrine) 1:80,000 (Lignospan® Special – latex free) 2.2mL Cartridges Solution for Injection (Administer)	
Indication	Local anaesthetic for restorative or periodontal treatment of permanent or deciduous teeth or where extraction of a deciduous tooth is indicated.
Inclusion criteria	• All individuals referred to the dental therapist/hygienist for routine dental treatment within the remit of the dental therapist/hygienist under GDC Scope of Practice guidance • Adults and children aged 4 years and over • Valid consent obtained.
Exclusion criteria	• Children under 4 years of age • Known hypersensitivity to lidocaine (lignocaine) or other local amide anaesthetics or sodium metabisulphite • Congenital or idiopathic methaemoglobinaemia • Partial or complete heart block, bradycardia • Any individual with asthma or have suffered breathing difficulties from using medicines which contain sulphites or metabisulphites • Any individual suffering from uncontrolled/severe hypertension, coronary disease or valvular cardiac disease • Individuals currently taking or taken in the past two weeks MAOI's, tricyclic antidepressants, serotonin/noradrenaline reuptake inhibitors antidepressants or phenothiazines • Individuals receiving beta blockers – concurrent use can cause bradycardia and hypertension • Advanced liver disease • Severe renal dysfunction • Acute intermittent porphyria • Pheochromocytoma • Infection or inflammation in the region of the proposed injection • Any individual where the maximum dosage of local anaesthesia has been given but anaesthesia remains inadequate.
Precautions and special warnings	Individuals with any of the precautions/special warnings listed below should be discussed with a dentist prior to treatment. Local anaesthetics, especially those containing adrenaline, should be administered with caution to individuals with peripheral vascular disease, arrhythmias, heart failure, hypotension, impaired cardiac function, epilepsy, advanced diabetes, severe anaemia or circulatory failure from whatever cause, renal or hepatic disease, thyrotoxicosis or any other pathological condition that might be aggravated by the effects

Lidocaine Hydrochloride 2% And Adrenaline (Epinephrine) 1:80,000 (Lignospan® Special – latex free) 2.2mL Cartridges Solution for Injection (Administer)	
	of adrenaline. Adrenaline may induce anginal pain in individuals suffering from ischaemic heart disease. The lowest dose leading to effective anaesthesia should be used in people over 70 years old and in people with renal or hepatic impairment. The risk of bleeding should be considered in people receiving treatment with antiplatelets/anticoagulants. Serious interactions between medicines and local anaesthetic preparations used in dental practice are exceedingly rare. Clinically relevant interactions are possible when more than 2 cartridges of a 1:80,000 adrenaline-containing solution are used with diuretics. The dosage of anaesthetic should be reduced in individuals that are using sedatives, e.g. to reduce apprehension. General consideration of nursing mothers (see SmPC regarding breastfeeding). Refer to BNF and SmPC for complete list. **N.B.** Healthcare professionals should not administer under this PGD if they feel that it is inappropriate for the individual or there are any contraindications for the medicine, refer to dentist.
Legal status	Lidocaine hydrochloride 2% and adrenaline (epinephrine) 1:80,000 (Lignospan Special®) is a Prescription-only Medicine (POM).
Dose/Maximum total dose	**N.B.** The doses outlined below are a guide as to the quantities of local anaesthetic to be administered. However, care should be taken to ensure treatment of individuals is based on weight and overall medical health, and not just the individual's age. One cartridge of 2.2mL of solution for injection contains 44mg of lidocaine hydrochloride and 27.5micrograms of adrenaline **Adults:** 2.2mL (a full single cartridge) is generally sufficient for adults - two cartridges can be used in case of large interventions. **Maximum total dose** - 4.4mL (two full cartridges) per appointment **Adolescents (aged 12 to 18 years of age) and the elderly:** 1.8mL. **Maximum total dose** - 3.6mL per appointment

Lidocaine Hydrochloride 2% And Adrenaline (Epinephrine) 1:80,000 (Lignospan® Special – latex free) 2.2mL Cartridges Solution for Injection (Administer)	
	Children: Age 4 – 6 years: 0.9mL **Maximum total dose** - 1.8mL per appointment Age 6 -11 years: 1.35mL **Maximum total dose** - 2.7mL per appointment
Frequency of dose/Duration of treatment	If anaesthesia is not adequate, a further dose of the same or alternative anaesthetic solution or an alternative route may be used up to the total dose/number of cartridges stated as per the Dosage/Maximum total dose section above.
Maximum or minimum treatment period	N/A
Route/Method of administration	By sub-mucosal infiltration or nerve block injection. To be injected slowly with appropriate precautions to ensure it is not injected directly into a blood vessel. Part used cartridges **must not** be used for more than one individual.
Quantity to be administered	See Dosage/Maximum total dose section above.
Potential adverse reactions	These are generally dose related, e.g. through excess dosage, rapid absorption or unintended intra-vascular administration. Hypersensitivity reactions or idiosyncrasy or decreased tolerance can also occur. **Central Nervous System:** Light-headedness, nervousness, apprehension, euphoria, confusion, dizziness, headaches, malaise, agitation, tinnitus, drowsiness, blurred or double vision, nausea, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. Drowsiness is usually an early sign of a high blood level and can occur due to rapid absorption. **Cardiovascular system:** These are usually depressant and characterised by bradycardia, or tachycardia, palpitations, hypotension, and cardiovascular collapse which may lead to cardiac arrest.

Lidocaine Hydrochloride 2% And Adrenaline (Epinephrine) 1:80,000 (Lignospan® Special – latex free) 2.2mL Cartridges Solution for Injection (Administer)	
	Allergic reactions: Allergic reactions due to sensitivity are rare. These are usually characterised by cutaneous lesions, urticaria, oedema or anaphylactoid reactions. Refer to BNF and SmPC for complete list.
Advice (Verbal/written)	Temporary loss of feeling - numbness for possibly up to 3 - 4 hours. • Post-operative care – advise individual to avoid hot drinks, smoking or chewing hard foods till return of full sensations. Make individual aware of risk to lip or cheek of biting at any time during this period of numbness Advise individuals that if they experience side effects, including dizziness or blurred vision, not to drive or operate machinery until the effects have disappeared.
Monitoring (if applicable)	• Monitor for adverse reactions for approximately 15 minutes.
Storage	Store below 25ºC. Keep the cartridges in the outer carton tightly closed, in order to protect from light. Do not freeze.

Mepivacaine Hydrochloride 3% (Scandonest® 3% Plain) 2.2mL Cartridges Solution for Injection (Administer)	
Indication	Local anaesthetic for restorative or periodontal treatment of permanent or deciduous teeth or where extraction of a deciduous tooth is indicated.
Inclusion criteria	• All individuals referred to the dental therapist/hygienist for routine dental treatment within the remit of the dental therapist/hygienist under GDC Scope of Practice guidance • Adults and children over 4 years • Valid consent obtained.
Exclusion criteria	• Children under 4 years of age • Hypersensitivity to any component of the product • Any individual where the medical history is for any reason incomplete or unavailable • Pregnancy • Any individual where the maximum dosage of local anaesthesia has been given but anaesthesia remains inadequate • Infection or inflammation in the region of the proposed injection • Individuals with severe cardiac rhythm disturbances or complete heart block.
Precautions and special warnings	Do **not** give by intravascular injection. Individuals with any of the following precautions/special warnings should be discussed with a dentist prior to treatment: • Breastfeeding – nursing mothers are advised not to breastfeed within 10 hours following anaesthesia with Scandonest® • Renal or Hepatic disease – risk of development of higher plasma concentrations • Inflammation or sepsis at injection site can alter the pH of the injection and cause a decrease or loss of anaesthetic effect • The dosage of anaesthetic should be reduced in individuals that are using sedatives, e.g. to reduce apprehension. Refer to BNF and SmPC for complete list. **N.B.** Healthcare professionals should not administer under this PGD if they feel that it is inappropriate for the individual, refer to dentist.

Mepivacaine Hydrochloride 3% (Scandonest® 3% Plain) 2.2mL Cartridges Solution for Injection (Administer)	
Legal status	Mepivacaine Hydrochloride 3% (Scandonest® 3% Plain) is a Prescription-only Medicine (POM).
Dose/Maximum total dose	**N.B.** The doses outlined below are a guide as to the quantities of local anaesthetic to be administered. However, care should be taken to ensure treatment of individuals is based on weight and overall medical health, and not just the individual's age. Each cartridge of 2.2mL of solution for injection contains 66mg of mepivacaine hydrochloride. **Adults and adolescents (aged 14 to 17 years):** 2.2mL (one full cartridge) for routine work. **Maximum total dose** - 4.4mL (2 full cartridges) per appointment. **Children:** Age 4 - 6 years – 1.1mL to 1.6mL **Maximum total dose** - 2.2mL (1 full cartridge) per appointment. Age 6 -14 years – usual dose 1.6mL **Maximum total dose** - 3.3mL (1 and a half full cartridge) per appointment. The lowest dose that results in effective anaesthesia must be used to avoid adverse effects due to high blood levels. Reduced doses should be administered in elderly people, and people with renal or hepatic impairment.
Frequency of dose/Duration of treatment	If anaesthesia is not adequate, a further dose of the same or alternative anaesthetic solution or an alternative route may be used up to the total dose/number of cartridges stated as per the Dosage/Maximum total dose section above.
Maximum or minimum treatment period	N/A
Route/Method of administration	By sub-mucosal infiltration or nerve block injection. To be injected slowly with appropriate precautions to ensure it is not injected directly into a blood vessel. Part used cartridges **must not** be used for more than one individual.

Mepivacaine Hydrochloride 3% (Scandonest® 3% Plain) 2.2mL Cartridges Solution for Injection (Administer)	
Quantity to be administered	See Dosage/Maximum total dose section above.
Potential adverse reactions	These are generally dose related, e.g. through excess dosage, rapid absorption or unintended intra-vascular administration. Hypersensitivity reactions, idiosyncrasy or decreased tolerance can also occur. **Central Nervous System:** Light-headedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, blurred or double vision, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. Drowsiness is usually an early sign of a high blood level and can occur due to rapid absorption. **Cardiovascular system:** These are usually depressant and characterised by bradycardia, hypotension, and cardiovascular collapse which may lead to cardiac arrest. **Allergic reactions:** Allergic reactions due to sensitivity are rare. These are usually characterised by cutaneous lesions, urticaria, oedema or anaphylactoid reactions. Refer to BNF and SmPC for complete list**.**
Advice (Verbal/written)	Temporary loss of feeling - numbness for possibly up to 3 - 4 hours. • Post-operative care – advise individual to avoid hot drinks, smoking or chewing hard foods till return of full sensations. Make individual aware of risk to lip or cheek of biting at any time during this period of numbness. Advise individuals that if they experience side effects, including dizziness or blurred vision, not to drive or operate machinery until the effects have disappeared.
Monitoring (if applicable)	• Monitor for adverse reactions for approximately 15 minutes.
Storage	The product is to be stored below 25ºC. To prevent from light and to aid stability, each time cartridges are taken remember to replace the blister into the carton and close this latter.

Dental Formulary

Lidocaine 2.5% And Prilocaine 2.5% (Oraqix®) 1.7g Cartridges Periodontal Gel (Administer)	
Indication	Indicated in adults for localised anaesthesia in periodontal pockets for diagnostic and treatment procedures such as probing, scaling and/or root planing in adults.
Inclusion criteria	• All individuals 18 years of age and over referred to the dental therapist/hygienist for routine dental treatment within the remit of the dental therapist/hygienist under GDC Scope of Practice guidance • Periodontal treatment cases • Valid consent obtained.
Exclusion criteria	• Under 18 years of age • Hypersensitivity to any component of the product • Pregnancy – refer to dentist • Individual's not requiring or refusing anaesthesia • Any individual where the medical history is for any reason incomplete or unavailable • Any individual where the maximum dosage of local anaesthesia has been given but anaesthesia remains inadequate • Oraqix® should be avoided in individuals with anaemia or congenital or acquired methaemoglobinaemia • Oraqix® is contraindicated in individuals with recurrent porphyria • Oraqix® should not be applied to ulcerative lesions or during acute oral cavity infections.
Precautions and special warnings	Individuals with any of the following precautions/special warnings should be discussed with a dentist prior to treatment: • Use with caution in individuals with severe renal or hepatic impairment • Use with caution in individuals with severe cardiac rhythm disturbances or heart block • Use with caution in individuals who are in remission from porphyria or who are asymptomatic carriers of the mutated genes that are responsible for the development of porphyria Refer to BNF and SmPC for complete list. **N.B.** Healthcare professionals should not administer under this PGD if they feel that it is inappropriate for the individual, refer to dentist.

Lidocaine 2.5% And Prilocaine 2.5% (Oraqix®) 1.7g Cartridges Periodontal Gel (Administer)	
Legal status	Oraqix® (2.5% Lidocaine / 2.5% Prilocaine) Periodontal Gel is a Prescription-only Medicine (POM).
Dose/Maximum total dose	**N.B.** The doses outlined below are a guide as to the quantities of local anaesthetic to be administered. However, care should be taken to ensure treatment of individuals is based on weight and overall medical health, and not just the individual's age. One cartridge (1.7g) or less is sufficient for one quadrant of dentition. (8.5g gel). **Maximum total dose per appointment:** Five cartridges (8.5g gel).
Frequency of dose/Duration of treatment	As required for treatment appointment up to maximum allowable dose.
Maximum or minimum treatment period	N/A
Route/Method of administration	Periodontal use. Do **not** give by injection – for use with appropriate applicators only.
Quantity to be administered	See Dosage/Maximum total Dose section above.
Potential adverse reactions	**Allergy:** Allergic reactions may occur in sensitive individuals. Significant adverse effects on intact skin are unlikely. Contact with mucous membranes may cause irritation and/or numbness (loss of sensation). **Potential Side-effects:** Headache, local pain, soreness, numbness, ulcer, irritation, redness, reaction, taste perversion, dizziness, pulsation, vesicles, oedema, burning, nausea. Allergic reactions. **Chronic Effects:** Chronic effects are unlikely to occur. Repeated exposure to high levels of an amide anaesthetic in animals produced adverse effects on the liver and CNS. **Inhalation (unlikely route of exposure) and Ingestion:** Systemic effects may include nervousness, confusion, drowsiness, blurred vision, vomiting, tremors, convulsions, respiratory depression, slowing of the heart rate, blood pressure drop and unconsciousness. Local effects may include allergic reaction, irritation and numbness (loss of sensation).

Lidocaine 2.5% And Prilocaine 2.5% (Oraqix®) 1.7g Cartridges Periodontal Gel (Administer)	
	Medical Conditions Aggravated by Exposure: Prilocaine may cause methaemoglobinaemia in high doses and so may aggravate congenital or idiopathic methaemoglobinaemia. Refer to BNF and SmPC for complete list**.**
Advice (Verbal/written)	Temporary loss of feeling - numbness for possibly up to 3 - 4 hours. • Post-operative care – advise individual to avoid hot drinks, smoking or chewing hard foods during temporary loss of feeling. Make individual aware of risk to lip or cheek of biting at any time during this period of numbness • Monitor for adverse reactions for approximately 15 minutes. Advise individuals that if they experience side effects, including dizziness or blurred vision, not to drive or operate machinery until the effects have disappeared.
Monitoring (if applicable)	• Monitor for adverse reactions for approximately 15 minutes.
Storage	Do not freeze.

Prilocaine Hydrochloride 30mg/mL With Felypressin 0.54 micrograms/mL (Citanest 3% With Octapressin® 0.066units/2.2mL) 2.2ml Cartridges Solution for Injection (Administer)	
Indication	Local anaesthetic for restorative or periodontal treatment of permanent or deciduous teeth or where extraction of a deciduous tooth is indicated.
Inclusion criteria	• Adults and children over 3 years • All individuals referred to the dental therapist/hygienist for routine dental treatment within the remit of the dental therapist/hygienist under GDC Scope of Practice guidance • Valid consent obtained.
Exclusion criteria	• Children under 3 years of age • Pregnancy - refer to dentist • Known hypersensitivity to local amide anaesthetics or to any component of the injectable formulation (see list of excipients in the SmPC • Anaemia or congenital or idiopathic methaemoglobinaemia • Partial or complete heart block • Advanced liver disease • Severe renal dysfunction • Infection or inflammation in the region of the proposed injection • Individuals taking sulphonamides (e.g. co-trimoxazole), or anti-malaria medicines • Any individual where the maximum dosage of anaesthesia has been given but anaesthesia remains inadequate.
Precautions and special warnings	Individuals with any of the following precautions/special warnings should be discussed with a dentist prior to treatment: • Breastfeeding – use with caution • Use with caution in individuals epilepsy, severe or untreated hypertension, impaired cardiac conduction, severe heart disease, impaired respiratory function, and in individuals with liver or kidney damage. Refer to BNF and SmPC for complete list. **N.B.** Healthcare professionals should not administer under this PGD if they feel that it is inappropriate for the individual, refer to dentist.
Legal status	Prilocaine Hydrochloride 30mg/mL With Felypressin 0.54micrograms/mL (Citanest 3% With Octapressin® 0.066units/2.2mL) is a Prescription-only Medicine (POM).

Prilocaine Hydrochloride 30mg/mL With Felypressin 0.54 micrograms/mL (Citanest 3% With Octapressin® 0.066units/2.2mL) 2.2ml Cartridges Solution for Injection (Administer)	
Dose/Maximum total dose	**N.B.** The doses outlined below are a guide as to the quantities of local anaesthetic to be administered. However, care should be taken to ensure treatment of individuals is based on weight and overall medical health, and not just the individual's age. **Adults:** 2.2mL (a full single cartridge) is generally sufficient for adults and children over 10 years old – 4.4mL (two cartridges) can be used in case of large interventions. **Total maximum dose of 10mL.** **Children under 10 years of age:** normally 1mL to 2mL dose. **Total maximum dose of 2mL.**
Frequency of dose/Duration of treatment	If anaesthesia is not adequate, a further dose of the same or alternative anaesthetic solution or an alternative route may be used up to the total dose/number of cartridges stated as per the Dosage/Maximum total dose section above.
Maximum or minimum treatment period	N/A
Route/Method of administration	By sub-mucosal infiltration or nerve block injection. To be injected slowly with appropriate precautions to ensure it is not injected directly into a blood vessel. Part used cartridges **must not** be used for more than one individual.
Quantity to be administered	See Dosage/Maximum total Dose section above.
Potential adverse reactions	Reactions to 3% Citanest® Dental with Octapressin® are very rare in the doses used in dental procedures. If adverse effects occur, they are similar in character to those observed with other local anaesthetics. These are generally dose related, e.g. through excess dosage, rapid absorption or unintended intra-vascular administration. Hypersensitivity reactions, idiosyncrasy or decreased tolerance can also occur.

Prilocaine Hydrochloride 30mg/mL With Felypressin 0.54 micrograms/mL (Citanest 3% With Octapressin® 0.066units/2.2mL) 2.2ml Cartridges Solution for Injection (Administer)	
	Allergic Reactions Allergic reactions (in the most severe instances anaphylactic shock) to local anaesthetics of the amide type are rare. **Acute Systemic Toxicity** Prilocaine can cause acute toxic effects if high systemic levels occur due to accidental intravascular injection, fast absorption or overdosage. **Methaemoglobinaemia** Methaemoglobinaemia may occur after the administration of prilocaine. The repeated administration of prilocaine, even in relatively small doses, can lead to clinically overt methaemoglobinaemia (cyanosis). With the dental dosage of prilocaine (1-5mL 3% Citanest® dental with Octapressin®, i.e. 30-150mg prilocaine hydrochloride 3% with felypressin 0.54micrograms/mL), the occurrence of methaemoglobinaemia in dental practice appears remote. However, gross overdosage in dental practice has been reported to cause methaemoglobinaemia. **Note.** Even low concentrations of methaemoglobin may interfere with pulse oximetry readings, indicating a false low oxygen saturation. Refer to BNF and SmPC for complete list**.**
Advice (Verbal/written)	Temporary loss of feeling - numbness for possibly up to 3 - 4 hours. • Post-operative care – lip/cheek biting/hot drinks/smoking/hard foods. Advise individual to avoid hot drinks, smoking or chewing hard foods during temporary loss of feeling. Make individual aware of risk to lip or cheek of biting at any time during this period of numbness. Advise individuals that if they experience side effects, including dizziness or blurred vision, not to drive or operate machinery until the effects have disappeared.
Monitoring (if applicable)	• Monitor for adverse reactions for approximately 15 minutes.
Storage	Do not store above 25°C.

Sodium Fluoride Dental Suspension 50mg/mL (Duraphat® Dental Suspension) (Administer)	
Indication	All individuals referred to the dental therapist/hygienist for routine dental treatment for whom the application of fluoride suspension would be beneficial: • Registered individuals up to 18 years of age as per the SDCEP guidelines • High caries risk • Caries prevention • Sensitivity • Precavitated lesions • Exposed cervical dentine • Xerostomia (dry mouth) • Individuals referred by oncology teams.
Inclusion criteria	• All individuals referred to the dental therapist/hygienist for routine dental treatment within the remit of the dental therapist/hygienist under GDC Scope of Practice guidance • Valid consent obtained.
Exclusion criteria	• Hypersensitivity to colophony or any component of the product • Individuals refusing fluoride treatment • Any individual where the medical history is for any reason incomplete or unavailable • Individuals with asthma • Presence of mouth ulcers • Presence of acute inflammation/stomatitis • Confirmed allergy to latex. (The container of this medicinal product contains latex rubber. May cause severe allergic reactions).
Precautions and special warnings	Individuals with any of the following precautions/special warnings should be discussed with a dentist prior to treatment: • Pregnant and breast feeding women as the varnish contains 33.8% ethanol (each dose contains up to 0.2g of alcohol) • Individuals who should avoid alcohol containing products • In individuals with gastric sensitivity, retching may exceptionally occur after high dose and extensive application.
Legal status	Sodium Fluoride Dental Suspension 50mg/ml (Duraphat® Varnish) is a Prescription-only Medicine (POM).
Dose/Maximum total dose	For deciduous teeth, up to 0.25mL to be applied.

Sodium Fluoride Dental Suspension 50mg/mL (Duraphat® Dental Suspension) (Administer)	
	For mixed dentitions, up to 0.40mL to be applied. For permanent teeth, up to 0.75mL to be applied **Maximum total dose per appointment as above.**
Frequency of dose/Duration of treatment	For caries prophylaxis the application is usually repeated every six months but more frequent applications (every 3 months) may be indicated. For hypersensitivity, 2 or 3 applications should be made within a few days.
Maximum or minimum treatment period	N/A
Route/Method of administration	To be applied as a thin layer to clean dry teeth using a brush, probe or swab.
Quantity to be administered	See Dosage/Maximum total Dose section above.
Potential adverse reactions	Side effects are rare but may include: • Irritation, inflammation and ulceration of the gums and mouth • Swelling of the oral tissues • Anaphylactic shock • Asthma attacks in known individuals with asthma • Nausea and retching. Refer to BNF and SmPC for complete list.
Advice (Verbal/written)	The individual/or person with parental responsibility should be advised: • Process is quick, simple and painless • The varnish will leave a yellow/brown tint/sticky residue on the teeth, which has a taste. This will be removed at next brushing • Application to the whole dentition should not be carried out on an empty stomach. • Do not brush teeth or chew food for four hours after application • On the day when the varnish has been applied, no high dose fluoride preparations, such as fluoride gels, should be used. The administration of fluoride supplements should be suspended for several days after applying the varnish.

Sodium Fluoride Dental Suspension 50mg/mL (Duraphat® Dental Suspension) (Administer)	
Monitoring (if applicable)	N/A
Storage	Do not store above 25ºC.

Dental Formulary

Sodium Fluoride Toothpaste 0.619% w/w (Duraphat® 2800ppm) (Supply)	
Indication	For the prevention and treatment of dental caries (coronal and root) in adults and children aged 10 years and over.
Inclusion criteria	• In-home prevention and treatment of dental caries in adults and children aged 10 years and over • All individuals referred to the dental therapist/hygienist as requiring an enhanced level of dental caries prevention within the remit of the dental therapist/hygienist under GDC Scope of Practice guidance • Valid consent obtained.
Exclusion criteria	• Under 10 years old • Hypersensitivity to the active ingredient or to any excipient. • Individuals with known sensitivities should be referred to a dentist.
Precautions and special warnings	The total amount of sodium fluoride in a 75mL tube of Duraphat® 2800ppm fluoride toothpaste is about 620mg which equates to 280mg fluoride. This is within the acceptable limits for the amount to be supplied at one time for safety purposes.
Legal status	Sodium Fluoride Toothpaste 0.619% W/V (Duraphat® 2800ppm) is a Prescription-only Medicine (POM). Labels must be written for each supply of the product and must include the following: • Individual's name. • The date the medicine is supplied. • The dose to be taken, how to take it and how often. The amount of medicine in the container and the strength and any cautions or warning messages that apply to the medicine are pointed out to the individual on the packaging and PIL.
Dose/Maximum total dose	Adults and children over 10 years old: use 1cm twice daily instead of the normal toothpaste. Issue one tube only. Repeat supply should be provided via dental prescription.
Frequency of dose/Duration of treatment	Daily usage in place of normal toothpaste for the length of time advised by the therapist/hygienist.
Maximum or minimum treatment period	N/A
Route/Method of administration	Prescribed amount applied using a toothbrush.

Sodium Fluoride Toothpaste 0.619% w/w (Duraphat® 2800ppm) (Supply)	
	Brush teeth carefully for 1 minute after meals using 1cm, before spitting out – twice daily.
Quantity to be supplied	Issue one tube at a time.
Potential adverse reactions	None known if used as recommended.
Advice (Verbal/written)	Advise that Duraphat® should not be swallowed.
Monitoring (if applicable)	N/A
Follow up	Regular dental examinations and caries risk assessments to be carried out.
Storage	Do not store above 25ºC.