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Grampian Highland Shetland

Patient Group Direction For The Supply/Administration Of Medicines As Included In The ENT Formulary For Nurses Working Within NHS Grampian, Highland And Shetland

Lead Author: Medicines Management Specialist Nurse NHSG	**Consultation Group**: See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/ENTF/1348	**Review Date:** September 2025 **Expiry Date:** September 2026	**Date Approved:** September 2023

NHS Grampian, Highland and Shetland 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 1

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD adapted from NHSG/PGD/ENTF/MGPG1129, Version 4	
Date of change	**Summary of Changes**	**Section heading**
May 2022	New PGD	

NoS Identifier: NoS/PGD/ENTF/1348

Keyword(s): PGD Patient Group Direction nurse ENT formulary betamethasone ciprofloxacin dexamethasone clotrimazole canesten fluocinolone gentamicin metronidazole mometasone furoate naseptin neomycin sulfate sofradex

Policy Statement: It is the responsibility of the individual healthcare professionals 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:	May 2022
	Completed:	September 2023
	Approved:	September 2023 (published – October 2023)
	Amended and re-authorised:	

Organisational Authorisations

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

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Mr Clive Brewis **Health Board:** NHSG **Title:** ENT Consultant and Clinical Lead **Contact email:** clive.brewis@nhs.scot **Signature:** ..... **Date:** 29/09/2023
Senior representative of the professional group who will provide care under the direction	**Name:** Patricia Dow **Health Board:** NHSG **Title:** ENT Nurse **Contact email:** patricia.dow@nhs.scot **Signature:** ..... **Date:** 02/10/2023
Lead author	**Name:** Jodie Allan **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** jodie.allan@nhs.scot **Signature:** ..... **Date:** 14/09/2023
Pharmacist	**Name:** Jane Wylie **Health Board:** NHSH **Title :** Clinical Pharmacy Team Lead for Surgery, Women and Children **Contact email:** jane.wylie1@nhs.scot **Signature:** ..... **Date:** 02/10/2023

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		28/09/2023

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		11/10/2023

Management and Monitoring of Patient Group Direction

PGD Consultative Group

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

Name:	**Title:**
Jodie Allan	**Lead Author:** Medicines Management Specialist Nurse NHSG
Jane Wylie	**Pharmacist**: Clinical Pharmacy Team Lead for Surgery, Women and Children
Mr Clive Brewis	**Medical Practitioner:** ENT Consultant and Clinical Lead NHSG
Patricia Dow	**Senior Representative:** ENT Nurse NHSG
Andrea Dryburgh	Nurse Manager ENT NHSG
Barbara Grubb	Senior Staff Nurse NHSH
Christina McDavitt	ENT Nurse NHSS
Alyson Newcombe	ENT Nurse NHSH

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Clinical indication to which this PGD applies

Definition of situation/ Condition	This Patient Group Direction (PGD) will authorise Ear Nose and Throat (ENT) Nurses to supply/administer medicines included in the ENT PGD Formulary (Appendix 3) to individuals attending outpatient clinics. 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). **Note:** Not all medicines contained in the ENT Nurse PGD Formulary (Appendix 3) will be used by all Boards. Therefore, ENT nurses working under this PGD should familiarise themselves with the medicines that are used in their own individual board and consult the appropriate medicine monograph before undertaking administration/supply.
Inclusion criteria	All individuals aged 2 years and over attending an ENT outpatient clinic provided they meet the inclusion criteria detailed within the individual medicine monographs (see Appendix 3) The medicines contained within Appendix 3 the ENT Nurse PGD Formulary may only be used within individual product monograph recommendations. The products listed in this formulary must be used only for the condition specified in the monograph. 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	• Individuals under 2 years of age • Individuals with specific contraindications to the use of the required medicine(s) listed in the product monograph (see Appendix 3) • Individuals who have had a previous adverse reaction to the product or their excipients • Where there is no valid consent.

Precautions and special warnings	• If there is any concern about the appropriate use of the medicine in the specific indications given within the PGD then medical advice should be sought. • If there is any doubt about the correct diagnosis, medical advice should be sought. • Precautions listed in the individual monographs must be taken into account.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Inform/refer to the relevant medical practitioner if individual/person with parental responsibility declines treatment. Document that the administration/supply was declined, the reason and advice given 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 POM (Prescription-only Medicines) or Pharmacy (P) medicines. 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.
Dosage/Maximum total dose	See individual medicine monographs.
Frequency of dose/Duration of treatment	See individual medicine monographs.
Maximum or minimum treatment period	See individual medicine monographs.
Route/Method of administration	See individual medicine monographs.

Quantity to be administered/ supplied	See individual medicine monographs.
Storage requirements	See individual medicine monographs.
Follow-up (if applicable)	See individual medicine monographs.
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. See individual medicine monographs for further medicine specific advice.
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.** **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. • 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	Registered nurses as recognised by the Nursing and Midwifery Council (NMC).
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 in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions. • 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 individual Board requirements.

	• Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis in-line with individual Board requirements. • Maintain their skills, knowledge and their own professional level of competence in this area according to their 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	Nurses working in ENT outpatient clinics within NHS Grampian, Highland and Shetland can be authorised to supply/administer the medicine(s) specified in this PGD by their Professional Line Manager/Consultant. 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 must be completed to allow audit of practice. An electronic/Hospital Electronic Prescribing and Medicines Administration (HEPMA) record of the screening and subsequent administration, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes.

<table>
<tr><td></td><td>If a paper record is used for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD, it should include as a minimum:
Date and time of supply/administration.
Individuals 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.
The name, dose, form, route (batch number, expiry date and site where appropriate for injectable medicines) of the medicine administered/supplied.
Record advice has been given as per monograph, or 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 individuals GP/relevant medical practitioner).
Depending on the clinical setting where supply/administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate:
Secondary Care Medical Notes
HEPMA
Individual service specific systems.</td></tr>
<tr><td>Audit</td><td>All records of the medicine(s) 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>Electronic Medicines Compendium
http://www.medicines.org.uk

<table>
<tr><th>Medicines</th><th>Date of Revision of the Text</th><th>Date Accessed</th></tr>
<tr><td>Betnesol® Betamethasone sodium phosphate eye, ear and nose drops 0.1%</td><td>11/01/21</td><td>05/09/23</td></tr>
<tr><td>Chlorhexidine dihydrochloride 0.5% and neomycin sulfate 0.5% Nasal Cream (Naseptin®)</td><td>13/06/22</td><td>05/09/23</td></tr>
</table>
</td></tr>
</table>

Medicines	Date of Revision of the Text	Date Accessed
Ciprofloxacin 3mg/mL/ and dexamethasone 1 mg/mL ear drops, suspension	16/01/20	05/09/23
Clotrimazole 1% with hydrocortisone 1%Cream (Canesten HC®)	12/07/22	05/09/23
Clotrimazole Cream 1%	26/07/18	05/09/23
Clotrimazole Solution 1% w/w (Canesten®)	07/07/22	05/09/23
Framycetin 0.5%, dexamethasone sodium metasulfobenzoate 0.05% and gramicidin 0.005% Eye/Ear Drops	04/05/23	05/09/23
Gentamicin 0.3% w/v and Hydrocortisone acetate 1% w/v Ear Drops	13/06/21	05/09/23
Lidocaine Hydrochloride 5% w/v and Phenylephrine Hydrochloride 0.5% w/v Topical Solution	02/05/17	05/09/23
Mometasone furoate 0.1% Ointment	02/03/23	05/09/23
Neomycin 0.5%, dexamethasone 0.1% and glacial acetic acid 2% Spray (Otomize®)	14/04/21	05/09/23

MHRA Products | Home
Fluocinolone acetonide Ointment 0.025% w/w (Synalar®) date of revision of text 17/11/21, date accessed 05/09/23.

British National Formulary and British National Formulary for Children https://www.bnf.org/products/bnf-online/ accessed 12/09/23.

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:

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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 they are 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 their individual code of professional practice and conduct.
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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 ENT Formulary For Nurses Working Within NHS Grampian, Highland And Shetland					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

Appendix 3

ENT PGD Formulary

Contents **Page No:**

Betamethasone Sodium Phosphate 0.1% Eye, Ear and Nose Drops (Supply/Administer)	
Indication	Treatment of non-infected inflammatory conditions of the ear.
Inclusion Criteria	As per main PGD inclusion criteria.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Bacterial, fungal or viral infections • Known or suspected perforation of the eardrum • Pregnancy.
Precautions and Special Warnings	Corticosteroids may reduce resistance to, and aid in, the establishment of bacterial, viral, or fungal infections and mask the clinical signs of an infection, preventing recognition of ineffectiveness of the antibiotic, or may suppress hypersensitivity reactions to substances in the product. Visual disturbance may be reported with systemic and topical corticosteroid use. If an individual presents with symptoms such as blurred vision or other visual disturbances, the individual should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.
Legal Status	Betamethasone sodium phosphate 0.1% eye, ear and nose drops is a Prescription Only Medicine (POM).
Dose/Maximum total dose	Adults and children: 2 drops instilled into the affected ear(s) twice a day.
Frequency of dose/Duration of treatment	7 days.
Maximum or minimum treatment period	7 days.
Route/Method of Administration	Topical use into the ear(s). This PGD does not cover administration into the eye or nose. The suspension should be warmed by holding the bottle in the hand for several minutes to avoid dizziness, which may result from the instillation of a cold suspension.

Betamethasone Sodium Phosphate 0.1% Eye, Ear and Nose Drops (Supply/Administer)	
	Then shake the bottle well before use. The individual should lie with the affected ear upward, and then the drops should be instilled. The outer ear lobe should be gently pulled upward and backward to allow the ear drops to flow down into the ear canal. This position should be maintained for around 5 minutes to facilitate penetration of the drops in the ear. Repeat, if necessary, for the opposite ear. To prevent contamination of the dropper tip in order to limit bacterial risks, care should be taken not to touch the auricle or the external ear canal and surrounding areas, or other surfaces with the dropper tip of the bottle.
Quantity to be supplied/ administered	**Supply** 1 x [10mL dropper bottle] **Administer** 2 drops into affected ear(s).
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects and does not represent all the product's known adverse effects: • Hypersensitivity reactions may occur within a few minutes or may be delayed and include irritation, burning, stinging, itching and dermatitis.
Advice	• May have a cold sensation when instilling drops • Do not use on a new body area • Seek medical advice if skin condition worsens whilst using a topical corticosteroid • Do not restart treatment without seeking medical advice • Maximum duration of use is 7 days Keep the ear dry between applications. Use a cotton wool and liquid soft paraffin (Vaseline®) plug as advised by clinic nurses.

Betamethasone Sodium Phosphate 0.1% Eye, Ear and Nose Drops (Supply/Administer)	
Follow up (If applicable)	Review as per individual treatment plan.
Storage	• Do not freeze • Do not store above 25^{o}C • Keep bottle in outer carton to protect from light • Once opened, discard after 28 days • Do not use after expiry date on the label and carton • Return any unused medication to your community pharmacy.

Chlorhexidine 0.1% With Neomycin 0.5% Nasal Cream (Supply/Administer)	
Indication	Used for prophylaxis to prevent staphylococci infection and to treat suspected staphylococci infection.
Inclusion Criteria	As per main PGD inclusion criteria.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Individuals who have previously shown a hypersensitivity reaction to neomycin or chlorhexidine, although such reactions are extremely rare. • Cream may contain arachis oil (peanut oil) which should not be used by individuals with a known allergy to peanuts. As there is a possible relationship between peanut and allergy to soya, individuals with a soya allergy should also avoid using this medicine. The cream formulation was changed in 2023 to remove arachis oil but creams produced prior to 2023 will still be in the supply chain until 2025. Check the box to confirm if the cream contains arachis oil (peanut oil) Naseptin Nasal Cream - Safety Alerts - (emc) (medicines.org.uk)
Precautions and Special Warnings	Use with caution in elderly individuals and individuals with impaired hearing.
Legal Status	Chlorhexidine 0.1% with neomycin 0.5% nasal cream is a Prescription-only Medicine (POM).
Dose/Maximum total dose	A small amount of cream should be placed on the little finger and applied to the inside of the nostril. This should be applied independently by the patient.
Frequency of dose/Duration of treatment	**For Prophylaxis:** apply twice daily for 7 days. **For Eradication of Infection:** apply four times a day for 10 days.
Maximum or minimum treatment period	N/A
Route/Method of Administration	For nasal application only. A small amount of cream is placed on the little finger and applied to the inside of each nostril.

Chlorhexidine 0.1% With Neomycin 0.5% Nasal Cream (Supply/Administer)	
Quantity to be supplied/ administered	See Dose/Maximum total dose section above for administration quantity. **Supply** Supply x 1 [15g tube] **Administer** A small amount of cream should be placed on the little finger and applied to the inside of the nostril. This should be applied independently by the patient
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: Irritative skin reactions can occasionally occur. Prolonged use of neomycin can lead to skin sensitivity.
Advice	Any adverse reactions stop treatment immediately and seek medical advice or emergency out of hour's service.
Follow up (If applicable)	Review as per individual treatment plan.
Storage	Store below 30°C. Do not freeze Do not use after the expiry date on the label and carton, and discard after 4 weeks of opening. Return any unused medication to your community pharmacy.

Ciprofloxacin/Dexamethasone 3mg/mL/1mg/mL Ear Drops Suspension (Supply/Administer)	
Indication	For treatment of acute otitis externa.
Inclusion Criteria	As per main PGD inclusion criteria.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Viral (i.e. varicella, herpes simplex) and fungal otic infections • Currently taking quinolone antibiotics • Previous adverse reaction to a quinolone antibiotic • Pregnancy • Breastfeeding.
Precautions and Special Warnings	If otorrhea persists after a full course of therapy, or if two or more episodes of otorrhea occur within six months, further evaluation is recommended to exclude an underlying condition such as cholesteatoma, foreign body, or a tumour. As with other antibacterial preparations, prolonged use of this product may result in overgrowth of non-susceptible organisms, including bacterial strains, yeast and fungi. If superinfection occurs, discontinue use and appropriate therapy should be initiated. If after one week of therapy some signs and symptoms persist, further evaluation is recommended to reassess the disease and the treatment. Corticosteroids may reduce resistance to, and aid in the establishment of bacterial, viral, or fungal infections and mask the clinical signs of an infection, preventing recognition of ineffectiveness of the antibiotic, or may suppress hypersensitivity reactions to substances in the product. Visual disturbance may be reported with systemic and topical corticosteroid use. If an individual presents with symptoms such as blurred vision or other visual disturbances, the individual should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.
Legal Status	Ciprofloxacin/Dexamethasone 3mg/mL/1mg/mL ear drops suspension is a Prescription-only Medicine (POM).

Ciprofloxacin/Dexamethasone 3mg/mL/1mg/mL Ear Drops Suspension (Supply/Administer)	
Dose/Maximum total dose	Instil four drops in the affected ear(s) twice a day for 7 days.
Frequency of dose/Duration of treatment	See Dose/Maximum total dose section above.
Maximum or minimum treatment period	Up to a maximum of 7 days.
Route/Method of Administration	For otic use only. The suspension should be warmed by holding the bottle in the hand for several minutes to avoid dizziness, which may result from the instillation of a cold suspension. Then shake the bottle well before use. The individual should lie with the affected ear upward, and then the drops should be instilled. The outer ear lobe should be gently pulled upward and backward to allow the ear drops to flow down into the ear canal. This position should be maintained for around 5 minutes to facilitate penetration of the drops in the ear. Repeat, if necessary, for the opposite ear. To prevent contamination of the dropper tip in order to limit bacterial risks, care should be taken not to touch the auricle or the external ear canal and surrounding areas, or other surfaces with the dropper tip of the bottle.
Quantity to be supplied/ administered	See Dose/Maximum total dose section above for administration quantity. **Supply** Supply x1 [5mL dropper bottle]. **Administer** Instil four drops in the affected ear(s).
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects.

Ciprofloxacin/Dexamethasone 3mg/mL/1mg/mL Ear Drops Suspension (Supply/Administer)	
	The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: Ciprofloxacin/Dexamethasone 3mg/mL/1 mg/mL suspension ear drop treatment should be stopped if irritation, sensitisation, or super-infection occur. Ear pain and ear discomfort may occur. Fungal ear infection. General: paraesthesia.
Advice	• Avoid hearing aids, indwelling earphones or using cotton buds/tissues in ear • May have a cold sensation when instilling drops • Advise individual not to touch the site of application and that the drops may cause irritation. • Keep the ear dry between applications. Use a cotton wool and liquid soft paraffin (Vaseline®) plug as advised by clinic nurses. • Complete treatment as per instructions
Follow up (If applicable)	Review individual within 7 - 14 days in nurse led clinic or in line with local protocols. Sooner if no improvement or worsening symptoms. Out of hour's service in an emergency.
Storage	Do not freeze. Keep the bottle in the outer carton in order to protect from light. Keep the bottle tightly closed when not in use. Keep the bottle until the completion of the treatment. Do not use after the expiry date on the label and carton, and discard after 4 weeks of opening. Return any unused medication to your community pharmacy.

Clotrimazole Cream 1% (Administer)	
Indication	For the treatment of skin infections caused by dermatomycoses due to moulds and other fungi, (e.g. *Trichophyton* species) or yeasts (*Candida* species).
Inclusion Criteria	As per main PGD inclusion criteria.
Exclusion Criteria	As per main PGD exclusion criteria.
Precautions and Special Warnings	This product contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).
Legal Status	Clotrimazole Cream 1% is a Pharmacy (P) medicine.
Dose/Maximum total dose	Application by the health care professional - approximately 1mL per application. **Maximum total dose allowed under this PGD is 2mL.**
Frequency of dose/Duration of treatment	Up to two applications.
Maximum or minimum treatment period	N/A
Route/Method of Administration	For otic use only. Apply sparingly by syringe to line the ear canal without blocking the individual's hearing. 1mL syringe is filled with Clotrimazole Cream 1% from a 20g tube using a clean technique, the tube is then re-used within its expiry date after first opening as required in clinic.
Quantity to be administered	See Dose/Maximum total dose section above for administration quantity.
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: Irritative skin reactions can occasionally occur.

Clotrimazole Cream 1% (Administer)	
Advice	Keep the ear dry between applications. Use a cotton wool and liquid soft paraffin (Vaseline) plug as advised by clinic nurses.
Follow up (If applicable)	Review as per individual treatment plan. Sooner if no improvement or worsening symptoms. Out of hour's service in an emergency.
Storage	Do not store above 25°C.

Clotrimazole and Hydrocortisone Cream 10mg/g 10mg/g (Supply/Administer)	
Indication	Treatment of fungal infection by susceptible organisms where inflammation co-exists, particularly for initial treatment (up to 7 days; treatment with antifungal preparation may need to continue for up to 21 days). For treatment of outer conchal area, pinnal area and ear canal.
Inclusion Criteria	As per main PGD inclusion criteria.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Any untreated bacterial or viral skin diseases • Pregnancy • Cold sores/acne • Vaccination reactions. **Note:** Other contra-indications as listed in the SmPC do not apply when being used for indication above **only**.
Precautions and Special Warnings	Corticosteroids may reduce resistance to and aid in, the establishment of bacterial, viral, or fungal infections and mask the clinical signs of an infection, or may suppress hypersensitivity reactions to substances in the product. Visual disturbance may be reported with systemic and topical corticosteroid use. If an individual presents with symptoms such as blurred vision or other visual disturbances, the individual should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma, or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. The product contains cetostearyl alcohol, which may cause local skin reactions, e.g. contact dermatitis.
Legal Status	Clotrimazole and hydrocortisone 10mg/g/10mg/g is a Pharmacy (P) medicine.
Dose/Maximum total dose	Adults and infants: a small quantity of preparation should be thinly and evenly applied to the affected area twice daily and rubbed in gently.

Clotrimazole and Hydrocortisone Cream 10mg/g 10mg/g (Supply/Administer)	
Frequency of dose/Duration of treatment	Cream should be thinly and evenly applied to the affected area twice daily and rubbed in gently. Treatment should be for a maximum of 7 days. If the acute symptoms have subsided after about 7 days but treatment is still required, this may be carried out with the corticoid-free preparation intended for this purpose.
Maximum or minimum treatment period	Maximum 7 days.
Route/Method of Administration	Topical use.
Quantity to be supplied/ administered	**Supply** Supply x 1 [30g tube]. **Administer** A small quantity of preparation should be thinly and evenly applied to the affected area and rubbed in gently.
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects and does not represent all the product's known adverse effects: • Skin and subcutaneous tissue disorders: blisters, discomfort/pain, oedema, erythema, irritation, peeling/exfoliation, pruritus, rash, stinging/burning. • Following long-term corticosteroids use: atrophic changes including striae, skin thinning and telangiectasia. Advise patient to use short-term only (see under Advice).
Advice	Inform individual/carer, if providing supply: • Spread thinly to affected area • Wash hands after use • Maximum duration of use is 7 days • Do not use on a new body area (other than as instructed) • Keep the ear dry between applications. Use a cotton wool and liquid soft paraffin (Vaseline®) plug as advised by clinic nurses • Seek medical advice if skin condition worsens whilst using a topical corticosteroid • Do not restart treatment without seeking medical advice.

Clotrimazole and Hydrocortisone Cream 10mg/g 10mg/g (Supply/Administer)	
Follow up (If applicable)	Review as per individual treatment plan.
Storage	• Do not freeze • Do not store above 25ºC • Do not use after expiry date on the label and carton, or 6 months after first opening • Return any unused medicine to your community pharmacy.

Clotrimazole Solution 1% w/w (Canesten®) (Supply/Administer)	
Indication	Used to treat fungal infections of the outer ear (otitis externa) and middle ear (otomycosis).
Inclusion Criteria	As per main PGD inclusion criteria.
Exclusion Criteria	As per main PGD exclusion criteria.
Precautions and Special Warnings	If otorrhea persists after a full course of therapy, or if two or more episodes of otorrhea occur within six months, further evaluation is recommended to exclude an underlying condition such as cholesteatoma, foreign body, or a tumour.
Legal Status	Clotrimazole Solution 1% w/w (Canesten®) is a Pharmacy (P) medicine.
Dose/Maximum total dose	Instil two drops in the affected ear(s) three times a day for 14 days.
Frequency of dose/Duration of treatment	See Dose/Maximum total dose section above.
Maximum or minimum treatment period	Up to a maximum of 14 days.
Route/Method of Administration	For otic use only. Shake the bottle well before use. The suspension should be warmed by holding the bottle in the hand for several minutes to avoid dizziness, which may result from the instillation of a cold suspension. The individual should lie with the affected ear upward, and then the drops should be instilled pulling several times on the aurical. This position should be maintained for around 5 minutes to facilitate penetration of the drops in the ear. Repeat, if necessary, for the opposite ear. To prevent contamination of the dropper tip in order to limit bacterial risks, care should be taken not to touch the auricle or the external ear canal and surrounding areas, or other surfaces with the dropper tip of the bottle.

Clotrimazole Solution 1% w/w (Canesten®) (Supply/Administer)	
	The area should be cleaned and 2 drops instilled in the affected ear three times a day.
Quantity to be supplied/ administered	See Dose/Maximum total dose section above for administration quantity. **Supply** Supply x1 [20mL dropper bottle]. **Administer** Instil 2 drops in the affected ear(s).
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: Irritative skin reactions can occasionally occur.
Advice	Inform individual/carer: • Cold sensation when instilling drops • How to instill drops effectively • Complete course of treatment • Keep ears dry • Avoid wearing hearing aids/ indwelling ear phones or using cotton buds/ tissues in ears.
Follow up (If applicable)	Review individual within 7 - 14 days of treatment. Sooner if no improvement or worsening symptoms. Contact nurse led clinic, GP or out of hours service in an emergency.
Storage	Do not store above 25°C. Keep in the outer package to protect from light Do not use after the expiry date on the label and carton, and discard after 12 weeks of opening. Return any unused medication to your community pharmacy.

Fluocinolone Acetonide 0.025% Ointment (Supply/Administer)	
Indication	For the treatment of acute otitis externa.
Inclusion Criteria	As per main PGD inclusion criteria.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Bacterial, fungal and viral infections • Pregnancy. **Note:** Other contra-indications as listed in the SmPC do not apply when being used for indication above **only** (see advice to be given to patient around only using on specified area and not on other parts of the body).
Precautions and Special Warnings	If otorrhea persists after a full course of therapy, or if two or more episodes of otorrhea occur within six months, further evaluation is recommended to exclude an underlying condition such as cholesteatoma, foreign body, or a tumour. Corticosteroids may reduce resistance to, and aid in, the establishment of bacterial, viral, or fungal infections and mask the clinical signs of an infection, or may suppress hypersensitivity reactions to substances in the product. Visual disturbance may be reported with systemic and topical corticosteroid use. If an individual presents with symptoms such as blurred vision or other visual disturbances, the individual should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. Fluocinolone acetonide is a potent topical corticosteroid. Rarely, long-term continuous or inappropriate use of topical corticosteroids can result in the development of rebound flares, reported as dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. Patients should be advised how much should be applied; how long to continue treatment; to use as instructed; to seek medical advice before using topical corticosteroids on a new body area; to return for medical advice if no improvement or worsening.
Legal Status	Fluocinolone Acetonide 0.025% ointment is a Prescription-only Medicine (POM).

Fluocinolone Acetonide 0.025% Ointment (Supply/Administer)	
Dose/Maximum total dose	Adults and children aged two year and over: a small quantity of preparation should be applied lightly to the affected area two times a day, and massaged gently and thoroughly into the skin.
Frequency of dose/Duration of treatment	See Dose/Maximum total dose and Maximum or minimum treatment period sections.
Maximum or minimum treatment period	Maximum 14 days. Seek medical advice if no improvement seen after 7 days.
Route/Method of Administration	Topical use.
Quantity to be supplied/ administered	**Supply** 1 x [30g tube]. **Administer** One application to affected area(s). Draw up 1mL into a syringe and apply a very small quantity to the ear canal bed.
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects and does not represent all the product's known adverse effects: • Dermatitis • Irritation at application site • Following long-term use: atrophic changes including striae, skin thinning and telangiectasia. Advise patient to use short-term only (see under Advice).
Advice	Inform individual/carer: • Spread thinly to affected area no more than twice per day • Wash hands after use • Maximum duration of use is 14 days • Do not use on a new body area • Keep the ear dry between applications. Use a cotton wool and liquid soft paraffin (Vaseline®) plug as advised by clinic nurses • Seek medical advice if skin condition worsens whilst using a topical corticosteroid

Fluocinolone Acetonide 0.025% Ointment (Supply/Administer)	
	• Do not restart treatment without seeking medical advice.
Follow up (If applicable)	Review as per individual treatment plan. Seek medical advice if no improvement seen after 7 days if no improvement within 7 days, or out of hours service in an emergency.
Storage	• Do not freeze • Do not store above 25ºC • Do not use after expiry date on the label and carton • Return any unused medicine to your community pharmacy.

Framycetin 0.5%, Dexamethasone Sodium Metasulfobenzoate 0.05% and Gramicidin 0.005% Eye/Ear Drops (Supply/Administer)	
Indication	Treatment of otitis externa.
Inclusion Criteria	As per main PGD inclusion criteria.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Otitis externa should not be treated when the eardrum is perforated because of the risk of ototoxicity • Previous individual or family history of ototoxicity with aminoglycosides (e.g. gentamicin, tobramycin, neomycin) • Pregnancy • Breastfeeding • Fungal or Viral ear infection.
Precautions and Special Warnings	If otorrhea persists after a full course of therapy, or if two or more episodes of otorrhea occur within six months, further evaluation is recommended to exclude an underlying condition such as cholesteatoma, foreign body, or a tumour. Treatment with corticosteroid/antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement, since prolonged use may lead to occult extension of infection due to the masking effect of the steroid. Topical application of aminoglycoside antibiotics into the middle ear carries a risk of hearing loss due to ototoxicity. This product must not be used if it is known or suspected that there is a perforation or a grommet/T tube in the tympanic membrane. Treatment with corticosteroid preparations should not be repeated or prolonged without regular review to exclude raised intraocular, pressure, cataract formation or unsuspected infections. Prolonged use may lead to skin sensitisation and the emergence of resistant organisms. Visual disturbance may be reported with systemic and topical corticosteroid use. If an individual presents with symptoms such as blurred vision or other visual disturbances, the individual should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as CSCR which have been reported after use of systemic and topical corticosteroids.

Framycetin 0.5%, Dexamethasone Sodium Metasulfobenzoate 0.05% and Gramicidin 0.005% Eye/Ear Drops (Supply/Administer)	
Legal Status	Framycetin 0.5%, dexamethasone sodium metasulfobenzoate 0.05% and gramicidin 0.005% eye/ear drops are a Prescription-only Medicine (POM).
Dose/Maximum total dose	Two or three drops instilled into the ear three or four times daily.
Frequency of dose/Duration of treatment	See Dose/Maximum total dose section above.
Maximum or minimum treatment period	Up to a maximum of 7 days.
Route/Method of Administration	For otic use only. Shake the bottle well before use. The suspension should be warmed by holding the bottle in the hand for several minutes to avoid dizziness, which may result from the instillation of a cold suspension. The individual should lie with the affected ear upward, and then the drops should be instilled pulling several times on the aurical. This position should be maintained for around 5 minutes to facilitate penetration of the drops in the ear. Repeat, if necessary, for the opposite ear. To prevent contamination of the dropper tip in order to limit bacterial risks, care should be taken not to touch the auricle or the external ear canal and surrounding areas, or other surfaces with the dropper tip of the bottle.
Quantity to be supplied/ administered	See Dose/Maximum total dose section above for administration quantity. **Supply** Supply x1 [10mL plastic dropper bottle] **Administer** Two or three drops instilled into the ear

Framycetin 0.5%, Dexamethasone Sodium Metasulfobenzoate 0.05% and Gramicidin 0.005% Eye/Ear Drops (Supply/Administer)	
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: Hypersensitivity reactions may occur, usually of the delayed type, leading to irritation, burning, stinging, itching and dermatitis. Long-term intensive topical use may lead to systemic effects.
Advice	Inform individual/carer: • Cold sensation when instilling drops • How to instill drops effectively • Keep ears dry • Avoid hearing aids/indwelling ear phones or using cotton buds/tissues in ear • Keep the ear dry between applications. Use a cotton wool and liquid soft paraffin (Vaseline) plug as advised by clinic nurses. • Complete treatment as per instructions.
Follow up (If applicable)	Seek medical advice if no improvement seen after 7 days or out of hour's service in an emergency.
Storage	Store below 25°C, do not refrigerate or freeze. Keep bottle in the outer carton to protect from light. Do not use after the expiry date on the label and carton, and discard after 4 weeks of opening. Return any unused medication to your community pharmacy.

Gentamicin 0.3% w/v and Hydrocortisone acetate 1% w/v Ear Drops (Supply/Administer)	
Indication	For treatment of eczema and infection of the outer ear (otitis externa).
Inclusion Criteria	As per main PGD inclusion criteria.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Myasthenia gravis • Known or suspected perforation of the ear drum • Pregnancy • Breastfeeding • Previous individual or family history of ototoxicity with aminoglycosides (e.g. gentamicin, tobramycin, neomycin)
Precautions and Special Warnings	If otorrhea persists after a full course of therapy, or if two or more episodes of otorrhea occur within six months, further evaluation is recommended to exclude an underlying condition such as cholesteatoma, foreign body, or a tumour. The condition of the ear drum must always be checked before this medicinal product is supplied/administered. The medicinal product must not be used if the integrity of the ear drum cannot be guaranteed. Gentamicin may cause irreversible partial or total deafness when given systemically or applied topically to open wounds or damaged skin. The effect is dose-related and is enhanced by renal and/or hepatic impairment. Topical application of aminoglycoside antibiotics into the middle ear carries a risk of hearing loss due to ototoxicity. This product must not be used if it is known or suspected that there is a perforation or a grommet/T tube in the tympanic membrane. Avoid long-term continuous use. Prolonged use may lead to skin sensitisation and the emergence of resistant organisms. Cross-sensitivity to other aminoglycoside antibiotics may occur. Visual disturbance may be reported with systemic and topical corticosteroid use. If an individual presents with symptoms such as blurred vision or other visual disturbances, the individual should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as CSCR which have been reported after use of systemic and topical corticosteroids.

Gentamicin 0.3% w/v and Hydrocortisone acetate 1% w/v Ear Drops (Supply/Administer)	
Legal Status	Gentamicin 0.3% w/v and Hydrocortisone acetate 1% w/v Ear Drops is a Prescription-only Medicine (POM).
Dose/Maximum total dose	2 - 4 drops instilled into the affected ear three to four times a day and at night.
Frequency of dose/Duration of treatment	Two to four drops instilled into the affected ear three to four times a day for a maximum of 7 days.
Maximum or minimum treatment period	Up to a maximum of 7 days.
Route/Method of Administration	For otic use only. Shake the bottle well before use. The suspension should be warmed by holding the bottle in the hand for several minutes to avoid dizziness, which may result from the instillation of a cold suspension. The individual should lie with the affected ear upward, and then the drops should be instilled pulling several times on the aurical. This position should be maintained for around 5 minutes to facilitate penetration of the drops in the ear. Repeat, if necessary, for the opposite ear. To prevent contamination of the dropper tip in order to limit bacterial risks, care should be taken not to touch the auricle or the external ear canal and surrounding areas, or other surfaces with the dropper tip of the bottle. The area should be cleaned and 2 - 4 drops instilled in the affected ear three to four times a day and at night. Alternatively, wicks medicated with this medicine may be placed in the external ear.

Gentamicin 0.3% w/v and Hydrocortisone acetate 1% w/v Ear Drops (Supply/Administer)	
Quantity to be supplied/ administered	See Dose/Maximum total dose section above for administration quantity. **Supply** Supply x1 [10mL dropper bottle]. **Administer** 2 – 4 drops instilled into the affected ear.
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: Gentamicin ear drop treatment should be stopped if irritation, sensitisation or super-infection occur. Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination of gentamicin with a corticosteroid should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case individuals should be monitored for systemic corticosteroid side-effects.
Advice	Inform individual/carer: • Cold sensation when instilling drops • How to instill drops effectively • Keep ears dry • Avoid hearing aids/indwelling ear phones or using cotton buds/tissues in ear • Keep the ear dry between applications. Use a cotton wool and liquid soft paraffin (Vaseline) plug as advised by clinic nurses. Complete treatment as per instructions.
Follow up (If applicable)	Seek medical advice if no improvement seen after 7 days if no improvement or symptoms worsen. Contact ENT nurse led clinic, GP practice or out of hours service in an emergency.

Gentamicin 0.3% w/v and Hydrocortisone acetate 1% w/v Ear Drops (Supply/Administer)	
Storage	Store below 25°C. Do not freeze or mix with other liquids. Keep bottle in the outer carton to protect from light. Do not use after the expiry date on the label and carton, and discard after 4 weeks of opening. Return any unused medication to your community pharmacy.

Lidocaine Hydrochloride 5% w/v and Phenylephrine Hydrochloride 0.5% w/v Topical Solution (Administer)	
Indication	Local anaesthetic solution for application to mucous membranes in the nose to provide analgesia and vasoconstriction to aid view of the nasal cavity.
Inclusion Criteria	As per main PGD inclusion criteria.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Under 12 years of age. • Hypersensitivity to Lidocaine Hydrochloride, local anaesthetics of the amide type or to Phenylephrine Hydrochloride. • Hypovolaemia, hypertension, acute ischaemic heart disease and complete heart block. • Thyrotoxicosis, glaucoma or urinary retention. • Individuals receiving other sympathomimetic drugs. • Lidocaine and phenylephrine topical solution should not be given to individuals taking monoamine oxidase inhibitors or within 2 weeks of their use (See SmPC for full details of drug interactions). • Pregnancy. • Breastfeeding.
Precautions and Special Warnings	Lidocaine and phenylephrine topical solution should be administered with caution to individuals taking β-adrenergic blocking agents and those with cardiovascular disease, diabetes mellitus, hypertension or hyperthyroidism, hypoxia, hypercapnia and porphyria. Lidocaine and phenylephrine topical solution should also be used with caution in individuals with epilepsy, impaired cardiac conduction, bradycardia, impaired hepatic function and in severe shock. Sympathomimetic-containing products should be used with great care in individuals suffering from angina. Use with caution if there is trauma to mucosa and/or sepsis in the area of proposed application. Oral topical anaesthesia may interfere with swallowing. Numbness of the tongue or buccal mucosa may increase the risk of biting trauma.

Lidocaine Hydrochloride 5% w/v and Phenylephrine Hydrochloride 0.5% w/v Topical Solution (Administer)	
Legal Status	Lidocaine Hydrochloride 5% w/v and Phenylephrine Hydrochloride 0.5% w/v Topical Solution is a Pharmacy (P) medicine. Each bottle contains 2.5mL of solution to be used as a spray; equivalent to 125mg of Lidocaine Hydrochloride and 12.5mg of Phenylephrine Hydrochloride.
Dose/Maximum total dose	1 to 8 sprays dependant on size of nasal cavity. Each spray is equivalent to 6.5mg of Lidocaine Hydrochloride and 0.65mg of Phenylephrine Hydrochloride. **Maximum total dose allowed under this PGD is 8 sprays equivalent to 52mg Lidocaine Hydrochloride and 5.2mg of Phenylephrine Hydrochloride.**
Frequency of dose/Duration of treatment	Once only application.
Maximum or minimum treatment period	N/A
Route/Method of Administration	Prime the pump dispenser by activating the pump 3 times. The pump dispenser will deliver a dose volume of 130 microlitre in each spray. Spray cotton wool with solution and then insert/administer to nose.
Quantity to be supplied/ administered	See Dose/Maximum total dose section above for administration quantity.
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: The lidocaine and phenylephrine topical solution may interfere with swallowing, and numbness of the tongue or buccal mucosa may increase the danger of biting trauma.

Lidocaine Hydrochloride 5% w/v and Phenylephrine Hydrochloride 0.5% w/v Topical Solution (Administer)	
	Local anaesthetics, (e.g. lidocaine) and sympathomimetics, (e.g. phenylephrine) may produce systemic adverse effects as a result of the raised plasma concentrations which ensue when the rate of absorption into the circulation exceeds the rate of breakdown, for example, by absorption of large amounts through mucous membranes or damaged skin or from highly vascular areas. **Possible Systemic Effects due to Lidocaine** The systemic toxicity of local anaesthetics mainly involves the central nervous system and the cardiovascular system. Excitation of the CNS may be manifested by restlessness, excitement, nervousness, dizziness, tinnitus, blurred vision, nausea and vomiting, muscle twitching and tremors, and convulsions. Numbness of the tongue and perioral region may appear as an early sign of systemic toxicity. Excitation may be transient and followed by depression with drowsiness, respiratory failure and coma. There may be simultaneous effects on the cardiovascular system with myocardial depression and peripheral vasodilatation resulting in hypotension and bradycardia; arrhythmias and cardiac arrest may occur. **Possible Systemic Effects due to Phenylephrine** Sympathomimetics may produce a wide range of adverse effects, most of which mimic the results of excessive stimulation of the sympathetic nervous system. These effects are mediated via the various types of adrenergic receptor, and the adverse effects of an individual drug depend to some extent upon its relative agonist activity on these different types of receptor at a given dose. Central effects of sympathomimetic agents include fear, anxiety, nervousness, restlessness, tremors, insomnia, confusion, irritability, psychotic states and epileptiform convulsions. Appetite may be reduced and nausea and vomiting may occur. Effects on the cardiovascular system are complex. Stimulation of alpha-adrenergic receptors produced vasoconstriction with resultant hypertension. This vasoconstriction is sometimes sufficiently severe to produce gangrene when sympathomimetics are infiltrated into the digits. The rise of blood pressure may produce cerebral haemorrhage and pulmonary oedema.

Lidocaine Hydrochloride 5% w/v and Phenylephrine Hydrochloride 0.5% w/v Topical Solution (Administer)	
	There may also be a reflex bradycardia, but stimulation of β_1-adrenergic receptors of the heart may produce tachycardia and cardiac arrhythmias, anginal pain, palpitations, and cardiac arrest: hypotension with dizziness and fainting, and flushing, may occur. Other effects that may occur with sympathomimetic agents include difficulty in micturition, particularly in the case of prostatic hypertrophy, and urinary retention, dyspnoea, weakness, altered metabolism, sweating, hyperpyrexia and hypersalivation. Headache is also common.
Advice	Avoid hot drinks/food for 30 minutes following administration. Give written advice leaflet.
Follow up (If applicable)	N/A
Storage	Do not store above 25°C. Keep in the original container. Use once and discard any remaining topical solution at the end of the session. Each bottle of topical solution is to be used for one patient only.

Mometasone Furoate 0.1% Ointment (Administer)	
Indication	Treatment of dry, itchy skin of the outer ear canal (otitis externa).
Inclusion Criteria	As per main PGD inclusion criteria.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Any current fungal, viral or bacterial infections • Psoriasis • Pregnancy • Breastfeeding.
Precautions and Special Warnings	If otorrhea persists after a full course of therapy, or if two or more episodes of otorrhea occur within six months, further evaluation is recommended to exclude an underlying condition such as cholesteatoma, foreign body, or a tumour. Mometasone Furoate 0.1% contains propylene glycol which may cause skin irritation.
Legal Status	Mometasone Furoate 0.1% w/w ointment is a Prescription-only Medicine (POM). **Note:** The use of Mometasone Furoate 0.1% as directed in this PGD is outside the terms of the marketing authorisation and constitutes an off-label use of the medicine. The individual should be informed prior to the administration that the use is off-label.
Dose/Maximum total dose	Once only application – approximately 1mL. **Maximum total dose allowed under this PGD is 1mL.**
Frequency of dose/Duration of treatment	Once only application.
Maximum or minimum treatment period	N/A
Route/Method of Administration	Apply sparingly by syringe to line the ear canal without blocking the individual's hearing. 1mL syringe is filled with Mometasone Furoate 0.1% ointment from a 30g tube using a clean technique, the tube is then re-used within its expiry date and for 12 weeks after first opening as required in clinic.

Mometasone Furoate 0.1% Ointment (Administer)	
Quantity to be administered	Approximately 1mL.
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: Mometasone Furoate 0.1% treatment should be stopped if irritation, sensitisation or super-infection occur.
Advice	Advice individual not to touch the site of application.
Follow up (If applicable)	Review as per individual treatment plan, sooner if no improvement or worsening symptoms. Seek medical advice or out of hours service in an emergency.
Storage	Store between 2° and 30°C. Do not use after the expiry date on the label and carton, and discard after 4 weeks of opening. Dispose of in accordance with the individual Board guidance on waste management.

Neomycin Sulfate/Dexamethasone/Glacial Acetic Acid 0.5%, 0.1% and 2% (Otimize®) Ear Spray (Supply/Administer)	
Indication	For treatment of acute otitis externa.
Inclusion Criteria	As per main PGD inclusion criteria.
Exclusion Criteria	As per main PGD exclusion criteria and additionally: • Known or suspected perforation of the eardrum • Where a tympanostomy tube (grommet) is in situ • Previous individual or family history of ototoxicity with aminoglycosides (e.g. gentamicin, tobramycin, neomycin) • Pregnancy • Breastfeeding.
Precautions and Special Warnings	If otorrhea persists after a full course of therapy, or if two or more episodes of otorrhea occur within six months, further evaluation is recommended to exclude an underlying condition such as cholesteatoma, foreign body, or a tumour. The condition of the ear drum must always be checked before this medicinal product is supplied/administered. The medicinal product must not be used if the integrity of the ear drum cannot be guaranteed. Neomycin may cause irreversible partial or total deafness when given systemically or applied topically to open wounds or damaged skin. The effect is dose-related and is enhanced by renal and/or hepatic impairment. Topical application of aminoglycoside antibiotics into the middle ear carries a risk of hearing loss due to ototoxicity. This product must not be used if it is known or suspected that there is a perforation or a grommet/T tube in the tympanic membrane. Avoid long-term continuous use. Prolonged use may lead to skin sensitisation and the emergence of resistant organisms. Cross-sensitivity to other aminoglycoside antibiotics may occur. Visual disturbance may be reported with systemic and topical corticosteroid use. If an individual presents with symptoms such as blurred vision or other visual disturbances, the individual should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such

Neomycin Sulfate/Dexamethasone/Glacial Acetic Acid 0.5%, 0.1% and 2% (Otimize®) Ear Spray (Supply/Administer)	
	as CSCR which have been reported after use of systemic and topical corticosteroids.
Legal Status	Neomycin Sulfate/Dexamethasone/Glacial Acetic Acid 0.5%/0.1%/2% ear spray (OTOMIZE®) is a Prescription-only Medicine (POM)
Dose/Maximum total dose	Adults and children aged two years and over: one metred dose to be administered into each affected ear three times daily.
Frequency of dose/Duration of treatment	Treatment should be continued until two days after symptoms have disappeared. Maximum duration of therapy 7 days. Seek further medical advice if no improvement within 7 days.
Maximum or minimum treatment period	Maximum 7 days.
Route/Method of Administration	For otic use only. Shake the bottle well before use. Before first use, press actuator down several times to obtain a fine spray. Each press delivers on metered dose. Do not inhale the spray. Administer spray directly by gently placing nozzle tip into ear opening and pressing down once on the actuator.
Quantity to be supplied/ administered	**Supply** Supply x 1 [5mL spray bottle] **Administer** One spray into each affected ear
Potential Adverse Reactions	Refer to the product Summary of Product Characteristics (SmPC) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: • Transient stinging or burning sensation first few days of treatment.

Neomycin Sulfate/Dexamethasone/Glacial Acetic Acid 0.5%, 0.1% and 2% (Otimize®) Ear Spray (Supply/Administer)	
	• Skin sensitisation/hypersensitivity reactions (immediate and delayed) leading to burning, stinging, itching, dermatitis and irritation.
Advice	Inform individual/carer: • Spray may cause irritation. Discontinue treatment if irritation or rash occurs and seek advice • Do not touch the site of application • Do not inhale spray • Keep the ear dry between applications. Use a cotton wool and liquid soft paraffin (Vaseline®) plug as advised by clinic nurses.
Follow up (If applicable)	Review as per individual treatment plan. Seek medical advice if no improvement within 7 days, or out of hours service in an emergency.
Storage	• Store upright. Keep bottle in outer carton to protect from light. Do not freeze. • Do not store above 25°C. • Do not use after expiry date on the label and carton, and discard 4 weeks after first opening. • Return any unused medicine to your community pharmacy.