

## PATIENT GROUP DIRECTION (PGD)

**Supply & Administration of SOFRADEX® EAR DROPS  
By Registered Nurses in ENT services at UHDB**

### Documentation details

|               |            |
|---------------|------------|
| Reference no: | UHDB 136   |
| Version no:   | V1         |
| Valid from:   | 21/02/2022 |
| Review date:  | 21/08/2024 |
| Expiry date:  | 20/02/2025 |

### Change history

| Version number | Change details                          | Date                 |
|----------------|---|----------------------|
| 1              | Update for Burton/Derby ENT Outpatients | 13 <sup>th</sup> May |
|                |   |                      |
|                |   |                      |

### Glossary

| Abbreviation | Definition |
|--------------|------------|
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**1. PGD template development (PGD Working Group)**

**PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD (or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version**

| Name            | Designation                          |
|-----------------|--------------------------------------|
| Adrian Thompson | Lead Consultant                      |
| Hayley Mills    | Sister, ENT outpatients – QHB        |
| Natasha Lucas   | Aural Care Nurse Practitioner – RDH  |
| Suzanne Smith   | Divisional Lead Pharmacist – Surgery |
|                 |                                      |
|                 |                                      |

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

| Name of antimicrobial pharmacist | Designation | Date Reviewed |
|----------------------------------|-------------|---------------|
| n/a                              | n/a         | n/a           |

## 2. Organisational authorisations

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

**University Hospitals of Derby & Burton NHS Foundation Trust** authorises this PGD for use by the services or providers listed below:

| Authorised for use by the following organisation and/or services      |
|---|
| ENT Outpatients at QHB, RDH and Outreach sites operated by UHDB staff |
| Limitations to authorisation  |
| Nil   |

| Organisational Authorisation (legal requirement).   |              |                                     |                   |
|---|--------------|-------------------------------------|-------------------|
| Role  | Name         | Sign                                | Date              |
| Medicines Safety Officer<br><br><i>Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)</i> | James Hooley | <b>Signed copy held in Pharmacy</b> | <b>21/02/2022</b> |

| Additional signatories (required as per legislation and locally agreed policy)                       |                        |   |                   |
|--|------------------------|---|-------------------|
| Role   | Name                   | Sign                                    | Date              |
| Divisional Lead Pharmacist –<br>Surgery<br><br><i>Clinical Pharmacist from PGD<br/>working group</i> | <b>Suzanne Smith</b>   | <b>Signed copy held in<br/>Pharmacy</b> | <b>18/02/2022</b> |
| Lead Consultant/Clinical<br>Director for ENT<br><br><i>Doctor</i>                                    | <b>Adrian Thompson</b> | Signed copy held in<br>Pharmacy         | <b>19/01/2022</b> |
| Sister- Outpatients at QHB<br><br><i>Registered Professional<br/>representing users of the PGD</i>   | <b>Hayley Mills</b>    | Signed copy held in<br>Pharmacy         | <b>25/01/2022</b> |

Local enquiries regarding the use of this PGD may be directed to [UHDB.PGDgovernance@nhs.net](mailto:UHDB.PGDgovernance@nhs.net)

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

### 3. Characteristics of staff

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| <b>Qualifications and professional registration</b>   | <ul style="list-style-type: none"> <li>Registered Nurse with a current NMC registration</li> </ul>   |
| <b>Initial training</b>   | <ul style="list-style-type: none"> <li>Completion of all Essential-to-role training as outlined in the UHDB PGD policy.</li> <li>Individual has read and understood full content of this PGD and signed authorisation (section 7)</li> <li>It is the responsibility of the individual Registered Nurse to remain updated, with evidence of continued professional development.</li> <li>Staff can undertake appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in the PGD.</li> <li>Have undertaken appropriate training for working under Patient Group Directions for the supply and administration of medicines, undertaken the Aural Care Training Course, The National Diploma in Primary Care for Practitioners and the Trust Drug Assessment.</li> </ul>   |
| <b>Competency assessment</b>  | <ul style="list-style-type: none"> <li>Supervision/Assessment from The ENT Sister/Lead</li> <li>Supervision/Assessment from The Aural Care Practitioner</li> <li>12 month Aural Care Competency book</li> <li>7 days course – The National Diploma in Primary Care for Practitioners</li> <li>Trust Drug Assessment</li> </ul> <p>Staff operating under this PGD are encouraged to review their competency using the <a href="#">NICE Competency Framework for health professionals using patient group directions</a></p> <p>Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the either authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.</p> |
| <b>Ongoing training and competency</b>  | <p>Has undertaken appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in the PGD. Has undertaken appropriate training for working under Patient Group Directions for the supply and administration of medicines, undertaken the Aural Care Training Course or attended The National Diploma in Primary Care for Practitioners</p> <p>Organisation PGD or medication training as required by employing Trust/organisation.</p>  |
| <p><b><i>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.</i></b></p> |  |

#### 4. Clinical condition or situation to which this PGD applies

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| <b>Clinical condition or situation to which this PGD applies</b>     | Ecematous inflammation and Infection to the Outer ear (Otitis Externa - 1 <sup>st</sup> line of treatment)   |
| <b>Criteria for inclusion</b>  | <ul style="list-style-type: none"> <li>• Consent gained – Verbal or Written</li> <li>• Patients aged 16 years or over presenting to Nurse Led ENT clinic with the above conditions</li> </ul>  |
| <b>Criteria for exclusion</b>  | <ul style="list-style-type: none"> <li>• Consent not gained</li> <li>• Hypersensitivity to any of the ingredients</li> <li>• Previous local or systemic reactions to the medicine or ingredients</li> </ul>  |
| <b>Cautions including any relevant action to be taken</b>            | <ul style="list-style-type: none"> <li>• Known or suspected perforation of tympanic membrane</li> <li>• Avoid prolonged use</li> <li>• Monitor for sensitivity reactions</li> <li>• Safety in pregnant and breastfeeding women has not been established. There is a risk of foetal ototoxicity where aminoglycoside antibiotic preparations are given in pregnancy.</li> </ul> <p>Staff Advice - Consult medical advice if an adverse event occurs. Document in medical notes. All serious adverse reactions must be reported under the National yellow card system.</p> |
| <b>Action to be taken if the patient is excluded</b>                 | <ul style="list-style-type: none"> <li>• Refer to medical staff for review and prescribing of alternative agent if appropriate.</li> <li>• Document reason for exclusion</li> </ul>  |
| <b>Action to be taken if the patient or carer declines treatment</b> | <ul style="list-style-type: none"> <li>• Document refusal</li> <li>• Action taken and advice given in nursing documentation</li> <li>• Refer to medical staff if appropriate</li> </ul> <p>Advise patient on alternative treatment</p>   |
| <b>Arrangements for referral for medical advice</b>                  | Monday to Friday 0900 – 5:30pm ENT Outpatients at QHB or RDH.<br>Outside these hours: ENT on call at QHB or RDH  |

#### 5. Description of treatment

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|---|---|
| <b>Name, strength &amp; formulation of drug</b>       | Framycetin 0.5%, Dexamethasone 0.05% w/v and 0.005% w/v of Gramicidin (Sofradex® Ear Drops) |
| <b>Legal category</b>                                 | POM   |
| <b>Route / method of administration</b>               | Topical to ear  |
| <b>Indicate any off-label use (if relevant)</b>       |   |
| <b>Dose and frequency of administration</b>           | 2-3 drops, 3-4 times a day  |
| <b>Duration of treatment</b>                          | Use for 7 days  |
| <b>Quantity to be supplied (leave blank if PGD is</b> | 1 bottle for each infected ear  |

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| <b>administration ONLY)</b>  | <i>Labelling must meet the requirements outlined in Trust PGD Policy and associated training. The Pharmacy department over-label packs to meet legal requirements for supply. If you do not hold these appropriately over-labelled packs in stock, then a supply to patients is not appropriate.</i>   |
| <b>Storage</b>   | <ul style="list-style-type: none"> <li>Once opened, use within 28 days – label with date, time and initials of who has issued it.</li> <li>Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below:</li> <li>Store below 25°C, do not refrigerate</li> </ul> <p>Available from the electronic Medicines Compendium website:<br/><a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>   |
| <b>Drug interactions</b>   | <p><i>The following interactions have been identified and should be considered where it is known a patient is on the following medicines:</i></p> <ul style="list-style-type: none"> <li>Nil relevant to topical administration</li> </ul> <p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website:<br/><a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>  |
| <b>Identification &amp; management of adverse reactions</b>        | <p>The following side effects are common:</p> <ul style="list-style-type: none"> <li>Delayed hypersensitivity, resulting in irritation, burning stinging, itching and dermatitis.</li> </ul> <p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website:<br/><a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>  |
| <b>Management of and reporting procedure for adverse reactions</b> | <ul style="list-style-type: none"> <li>Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <a href="https://yellowcard.mhra.gov.uk">https://yellowcard.mhra.gov.uk</a></li> <li>Record all adverse drug reactions (ADRs) in the patient's medical record.</li> <li>Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use.</li> </ul> <p>If anaphylaxis management may be required include this information here (e.g. adrenaline to be held/resuscitation team details)</p> |
| <b>Written information to be given to patient or carer</b>         | Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.   |
| <b>Patient advice / follow up treatment</b>                        | <ul style="list-style-type: none"> <li>Verbal advice on why the drug is being administered, action of the drug and subsequent management of condition</li> <li>Inform the individual/carer of possible side effects and their management</li> <li>The individual/carer should be advised to seek medical advice in the event of an adverse reaction</li> <li>Contact the clinic if irritation occurs</li> <li>3-4 week follow up in the Nurse Led Clinic</li> </ul>  |
| <b>Records</b>   | Details of the supply must be recorded in the patient's health records   |

and in a drug record stock book kept in the ENT Clinic. State “administered under PGD” with name and signature of authorised nurse. A second check should be obtained from a qualified healthcare practitioner before administration.

For EPMA:

Document the utilisation of the medicine under PGD by ordering the appropriate drug order item against the correct patient record in Nursing notes, Cito or V6.

Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following:

- name of individual, address, date of birth and GP with whom the individual is registered (if relevant)
- name of registered health professional
- name of medication supplied/administered
- date of supply/administration
- dose, form and route of supply/administration
- quantity supplied/administered
- batch number and expiry date (if applicable e.g. injections and implants)
- advice given, including advice given if excluded or declines treatment
- details of any adverse drug reactions and actions taken
- Confirm whether supplied and/or administered via Patient Group Direction (PGD)

Records should be signed and dated (or a password controlled e-records).

All records should be clear, legible and contemporaneous.

If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

## 6. Key references

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|-----------------------|---|
| <b>Key references</b> | <p>Update and include for each revision. In most cases a link to specific records in the examples below will be appropriate</p> <ul style="list-style-type: none"> <li>• Electronic Medicines Compendium <a href="#">Sofradex Ear / Eye Drops - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)</a></li> <li>• Electronic BNF <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a></li> <li>• NICE Medicines practice guideline “Patient Group Directions” <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> </ul> |
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## 7. Registered health professional authorisation sheet

**PGD Name [version]: ENT OPD – Sofradex [v1] PGD ref: UHDB 136**

**Valid from: 21/02/2022**

**Expiry date: 20/02/2025**

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

### Registered health professional

By signing this patient group direction you are indicating that

- a) You agree to and understand all content and commit to only work within this framework.
- b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
- c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

**I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.**

| Name | Designation | Signature | Date |
|------|-------------|-----------|------|
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### Authorising manager / Assessor

**I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.**

| Name | Designation | Signature | Date |
|------|-------------|-----------|------|
|      |             |           |      |

### Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.