

## Patient Group Direction (PGD) for the Administration of Trimovate® Cream

Clobetasone butyrate 0.05% w/w, Oxytetracycline 3% w/w,  
Nystatin 100,000 units/g

by Specialist Ear Care Nurses or Registered Nurses, with a Diploma in Primary Ear Care (or equivalent) employed or contracted by the Rotherham NHS Foundation Trust working within clinic or at the home of the patient who have successfully undertaken approved training and have been assessed as competent

<b>PGD Number:</b>	EC 4v3
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<b>Discipline:</b>	Primary Ear Care and Audiology Services
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Patient Group Directions are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

The majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration under a PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety), and where it is consistent with appropriate professional relationships and accountability.

- Each PGD has a unique identifier allocated by the pharmacist responsible for the management of Patient Group Directions for the organisation.
- Once a PGD has been given approval, the date on which the PGD comes into effect will be inserted by the pharmacist prior to submission onto the Rotherham NHS Foundation Trust intranet.
- The PGD must be reviewed within three years of authorisation
- PGDs that have failed to be reviewed and re-ratified ***must not*** be used past their expiry date and patient specific direction (prescriptions) must be used to authorise supply of medicines.

**Patient Group Direction for the Administration of  
Trimovate® Cream**

Clobetasone butyrate 0.05% w/w, Oxytetracycline 3% w/w, Nystatin 100,000 units/g by Specialist Ear Care Nurses or Registered Nurses, with a Diploma in Primary Ear Care (or equivalent) employed or contracted by the Rotherham NHS Foundation Trust working within clinic or at the home of the patient who have successfully undertaken approved training and have been assessed as competent

**1. Clinical Condition or situation to which the direction applies**

Drug Name: **Trimovate® Cream**

**(Clobetasone butyrate 0.05%, Oxytetracycline 3%, Nystatin 100,000 units/g)**

<p align="center"><b>Clinical Indications</b></p>	<ul style="list-style-type: none"> <li>• Acute or chronic otitis externa which is confirmed by otoscopy and is believed to have either a bacterial or fungal infective cause, where use of a more potent steroid is not required or cannot be used</li> <li>• Patient history may indicate repetitive episodes where there may be a risk of fungal infection</li> </ul>
<p align="center"><b>Criteria for Inclusion</b></p>	<ul style="list-style-type: none"> <li>• Informed consent of patient prior to examination</li> <li>• In children used sparingly and not in an airtight dressing</li> <li>• In adults applied by aural paint or where a dressing is in place for less than 7 days</li> </ul> <p>Patients presenting with any of the following:</p> <ul style="list-style-type: none"> <li>• Weepy, oedematous meatus/pinna</li> <li>• Meatus maybe partially or fully occluded with keratin debris</li> <li>• Red, inflamed, painful, meatus/pinna</li> <li>• Meatus maybe partially or fully occluded with discharge, which may be offensive</li> <li>• Otitis externa infected by micro-organisms sensitive to the anti-infectives in the ointment</li> <li>• Severe localised pain around an infected hair follicle (furuncle)</li> <li>• Any of the clinical indications can be found in a mastoid cavity</li> </ul>

<p><b>Criteria for Exclusion</b></p>	<ul style="list-style-type: none"> <li>• Patients with hypersensitivity to any component of the product</li> <li>• Children under one year of age</li> <li>• Children aged one to fourteen with occlusive dressing</li> <li>• Patients who have had this treatment for 7 days without clinical improvement</li> <li>• Pregnancy and breastfeeding</li> <li>• Viral infections, e.g. herpes simplex, chicken pox</li> <li>• Secondary infections due to dermatophytes, Pseudomonas or Proteus species</li> <li>• Acne vulgaris</li> <li>• Rosacea</li> <li>• Untreated bacterial, fungal or viral skin lesions</li> <li>• Widespread plaque psoriasis</li> </ul>
<p><b>Action if Patient declines Treatment</b></p>	<ul style="list-style-type: none"> <li>• Explain rationale for compliance to patients who do not wish to receive the medication</li> <li>• Inform/refer to specialist ear care nurse independent prescriber</li> <li>• Inform/refer to medical practitioner or ENT consultant</li> <li>• Document in patient's clinical record</li> </ul>
<p><b>Notes, Drug Interactions and Adverse Effects</b></p>	<ul style="list-style-type: none"> <li>• Local hypersensitivity reactions such as redness, erythema, rash, pruritus, urticaria, local skin burning and thinning of skin.</li> <li>• Trimovate may cause slight staining of hair, skin or fabric, but this can be removed by washing.</li> <li>• This list is not exhaustive. Refer to current BNF or Summary of Product Characteristics (SPC) for full details <a href="http://www.medicines.org.uk/emc">www.medicines.org.uk/emc</a></li> </ul>

## 2. Description of treatment

<p><b>Name, strength and formulation of drug</b></p>	<p>Trimovate® Cream Clobetasone butyrate 0.05% w/w, Oxytetracycline 3% w/w, Nystatin 100,000 units/g</p>
<p><b>Legal status</b></p>	<p>POM</p>
<p><b>Storage</b></p>	<p>Standards must be consistent with the Summary of Product Characteristics. All medication must be stored in a secure locked environment away from the direct patient care area below 25°C</p>

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<p><b>Dose/dose range</b></p>	<p>Apply sparingly in the external auditory meatus/pinna or apply using a wick dressing</p>
<p><b>Method /route</b></p>	<p>Following aural toilet, paint the ointment onto the affected area using cotton wool wound round a Jobson Horne probe Alternatively ointment may be applied sparingly on a ribbon gauze wick (adults 18 years and older only) which can remain in the meatus for less than 7 days All ear treatments must be carried out under direct vision using a light source</p>
<p><b>Frequency of administration</b></p>	<p>Optimum treatment is local meatal cleaning and application of ointment every 48 to 72 hours. If no improvement after 72 hours, consider taking a swab for culture and sensitivities and treat accordingly</p>
<p><b>Total dose number</b></p>	<p>In children aged up to seventeen years of age treatment should be limited to 7 days  In adults and children eighteen years of age and older, do not continue for more than 7days in the absence of clinical improvement.</p>
<p><b>Patient/carer advice and follow-up treatment</b></p>	<ul style="list-style-type: none"> <li>• Advise about nature of treatment</li> <li>• Give ear care education to prevent further problems</li> <li>• Give the patient a treatment information leaflet</li> <li>• Warn about possible sensitivities and side effects to treatment and instruct accordingly</li> <li>• Warn about staining of hair clothes and skin</li> </ul>

### 3. Records

1. The following records must be kept either on paper or computer based. Records should be kept locally and appropriate information passed to patient and relevant physicians.

- Patient's name, address, date of birth and consent given
- Name of medication
- Dose given.
- Brand, Batch Number and Expiry Date
- Signature & name of staff who administered or supplied the medication
- Route and site of administration (record all sites of administration to allow any reactions to be related to the site of the injection)
- Information & advice given to patient (including side effects)
- Details of any adverse drug reaction and actions taken, including documentation in the patient's clinical record. Any adverse reaction must be notified to relevant physicians.
- Referral arrangements (including self care)
- Date administered / supplied
- Any serious adverse events and any that may be attributable to black triangled drugs ▼ should be reported via Trust procedure and then to the MHRA using the yellow card system. [www.yellowcard.mhra.gov.uk](http://www.yellowcard.mhra.gov.uk)

#### 2. Audit Trail Data Collection

- A record of all individuals receiving treatment under this Patient Group Direction should be kept for audit purposes.
- **Reconciliation:** Stock balances should be reconcilable with Receipts, Administration, Records and Disposals on a patient-by-patient basis
- **Storage:** Standards must be consistent with the Summary of Product Characteristics. All medication must be stored in a secure locked environment away from the direct patient care area

## 4. Anaphylaxis - Emergency Treatment

Before administering any medication the possibility of anaphylaxis must be discussed and documented with the patient/carer prior to administration of any medication, which may produce an anaphylactic reaction.

When giving any medication the following should always be readily available:

- Access to the patients notes
- Adrenaline (Epinephrine) 1 in 1000 for intramuscular (i.m.) injection for use in emergency (NB: **check expiry dates** regularly )
- Syringes and needles of **suitable size** and capacity for dose.
- Access to a telephone

Adrenaline (Epinephrine) 1 in1000 (1mg/ml)	For intramuscular injection	
Age	Dose	Volume
Children under 6 years	150 micrograms	0.15ml
Children 6 – 12 years	300 micrograms	0.3ml
Adults and adolescents	500 micrograms	0.5ml
These doses may be repeated if necessary at 5-minute intervals according to blood pressure, pulse and respiratory function.		
Special cautions: see BNF 3.4.3	Epinephrine/ Adrenaline	

BNF Current Edition section 3.4.3

## 5. Professional Responsibility All practitioners

- The Lead Person and the practitioner will ensure he/she has the relevant training and is competent. He/she will attend training updates as appropriate.
- The practitioner will have due regard for their Professional Conduct and Guidelines for the Administration / Supply of Medicines
- It is the responsibility of the individual practitioner to ensure that he/she has appropriate knowledge of the product prior to proceeding. Refer to the Summary of Product Characteristics (SPC) or current BNF for further details on the product.
- Each individual must have received a personal copy of the PGD and signed on the list of individual professionals who may work within this PGD (kept with master copy of this PGD)
- Must be competent in the recognition and management of anaphylaxis.
- Must have access to all relevant DOH advice, including the relevant CMO letters or training and be competent in all aspects of immunisation including contraindications
- Must have access to a current copy of the BNF and *Immunisation against infectious disease* (The 'Green book') and comply with its recommendations (available on DH website – [www.dh.gov.uk/greenbook](http://www.dh.gov.uk/greenbook)) where appropriate.
- Annual attendance at the The Rotherham NHS Foundation Trust or workplace update on resuscitation skills and the management of anaphylaxis.
- Maintenance of own level of updating with evidence of continued professional development
- Regular updates in immunisation and vaccination where appropriate with particular reference to changes and national directives.
- **Such practitioners that meet the above criteria for training have The Rotherham NHS Foundation Trust's approval to administer/supply Trimovate® Cream (Clobetasone butyrate 0.05% w/w, Oxytetracycline 3% w/w, Nystatin 100,000 units/g) in accordance with this PGD without a doctor's prescription, and with the patient's informed consent.**
- Storage and handling of medicines should be carried out in accordance with The Rotherham NHS Foundation Trust's Medicines Management Policy.
- The EC Labelling and Leaflet Directive 92/27 applies to all supplies of medicine, including those supplied under Patient Group Directions and all products other than those immediately administered must be labelled for supply to patients.

Sources: HSC 200/026 Patient Group Directions; Current BNF; Current Summary of Product Characteristics. Refer to The Rotherham NHS Foundation Trust Procedure for Emergency Treatment of Anaphylactic Reactions and the UK Resuscitation Council Guidelines



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The original signed copy of this Patient Group Direction is held in the Pharmacy department.  
A copy of the signed document is held on file by the Lead Person.

## 6. Management of Patient Group Direction

This patient group direction is to be read, agreed to and signed by all healthcare professionals to whom it applies. One copy should be given to each practitioner with a copy being kept by the Lead Person with responsibility for PGDs within the organisation.

Developed by:-	Name & Title	Signature	Date
Lead doctor			
Lead Pharmacist	Christina Dezelak Medicines Information Pharmacist		
Lead health professional from group who will administer/supply medicine			

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This Patient Group Direction is authorised by us			
Title	Name (& Role if not stated)	Signed	Date
Local clinical manager e.g. nurse manager			
Responsible Consultant/ Clinician			
Chair of Drugs & Therapeutic Group	Osman Chohan Chief Pharmacist		

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The Registered Nurses named below, being employed or contracted by The Rotherham NHS Foundation Trust working within clinic or at the home of the patient have successfully undertaken approved training and have been assessed as competent and are authorised to supply/administer  
**Trimovate® Cream (Clobetasone butyrate 0.05%, Oxytetracycline 3%, Nystatin 100,000 units/g)**  
as specified under this Patient Group Direction

Register of Staff Trained and Assessed to Administer or Supply this Medicine:  
(additional sheets may be attached)

**“I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct”.**

Name of authorised practitioner	Signature of authorised practitioner	Clinical manager	Signature of clinical manager	Date