University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of CHLORAMPHENICOL 1% Eye Ointment / 0.5% Eye Drops
By Registered Practitioners working at University Hospitals of Derby and Burton

Documentation details

Reference no:	UHDB184
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Expiry date:	16/10/2025

Change history

Version number	Change details	Date
1	New UHDB format	09/2022

Glossary

Abbreviation	Definition

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
VICKI MEREDITH	SENIOR SISTER Eye Clinic
MR ANIL KUMAR	CONSULTANT OPHTHALMOLOGY
LISA NOCK	PHARMACIST

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
All UHDB sites and in clinics operated by UHDB staff at peripheral sites
Limitations to authorisation

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	James Hooley	Signed copy held by Pharmacy	17/10/2022

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Pharmacist	**LISA NOCK**	Signed copy held by Pharmacy	29/09/2022
Clinical Lead	**MR JAMES TILDESLEY**	Signed copy held by Pharmacy	06/10/2022
Senior Sister Outpatients	**VICKI MEREDITH**	Signed copy held by Pharmacy	27/09/2022

Local enquiries regarding the use of this PGD may be directed to 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

Qualifications and professional registration	- Qualified NMC Registered Nurse - Registered Health Care Professionals (who can legally operate under PGD'S) who have undergone additional training to administer drug outlined in this PGD and been assessed as competent.
Initial training	- Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Individual has read and understood full content of this PGD and signed authorisation (section 7) - Completion of on line PGD training - The Registered Healthcare Professional will undertake training and will ensure he/she is competent in all aspects of this treatment.
Competency assessment	Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions 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.
Ongoing training and competency	- Health care professionals must complete annual basic life support and anaphylaxis training to administer drugs under this PGD.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Superficial eye infections, including bacterial conjunctivitis, blepharitis, trichiasis, chalazion, stye, keratitis Prior to padding in cases of large corneal abrasion; Following removal of small foreign bodies Prior to and following minor operations and intravitreal injections Prophylaxis following suture removal; Prophylaxis following 'A' scan/ultrasound if carried out on day of surgery;
Criteria for inclusion	• Adults and children >2years diagnosed with / presenting with conditions to which PGD applies.
Criteria for exclusion	• Consent not gained • Previous local or systemic reactions to the medicine • Still experiencing pain 2 hours after removal of a foreign body • Treated with chloramphenicol on 2 or more other occasions in the previous 3 months (please note, patient/carer may have purchased this). • Known or suspected hypersensitivity to any of the ingredients • Pregnant or breastfeeding • Family or personal history of blood dyscrasias including aplastic anemia.
Cautions including any relevant action to be taken	• Ensure emergency drugs and equipment, including adrenaline, are available for the treatment of anaphylaxis and emergencies, according to local policy. • Seek further Medical advice for the following: • Previous bone marrow suppression during previous exposure to chloramphenicol.
Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes • Inform doctor for review and prescribing of alternative agent if appropriate
Action to be taken if the patient or carer declines treatment	• Document advice given • Inform doctor • Advise patient on alternative treatment
Arrangements for referral for medical advice	Inform doctor or suitably qualified specialist in ophthalmology. Discuss potential consequences/referral/records to be kept.

5. Description of treatment

Name, strength & formulation of drug	Chloramphenicol 1% w/w Eye ointment Chloramphenicol 0.5% Eye Drops (bottles for course or minims for single admin/prophylaxis)
Legal category	Prescription Only Medicine (POM)
Route / method of administration	Instilled into the affected eye(s)
Indicate any off-label use (if relevant)	None

Dose and frequency of administration	Ointment: Apply a 1cm line to affected eye (under the lower eyelid) 3 - 4 times a day Drops: Instil ONE drop into the affected eye(s) 4 times a day Prophylaxis: Instil ONE drop only per affected eye without a prescription (use minims)
Duration of treatment	5 – 7 days Treatment should be continued for at least 48 hours after eye appears normal.
Quantity to be supplied (leave blank if PGD is administration ONLY)	1 Tube / bottle prelabelled with instructions for administration Minims may be supplied where there is evidence of known allergy / intolerance to preservatives only. Boxes prelabelled with instructions for administration must be used.
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: • Ointment: Store below 25°C. Do not freeze. • Drops (bottles or minims): Refrigerate at 2-8 degrees Celsius • Protect from light.
Drug interactions	*The following interactions have been identified and should be considered where it is known a patient is on the following medicines:* • The concomitant administration of chloramphenicol with other drugs liable to depress bone marrow function should be avoided A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions	• Transient burning or stinging sensations • More serious side effects include bone marrow depression and rarely aplastic anaemia, angioneurotic oedema, anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis have been reported and are causes for discontinuation. • Allergic reactions including red eyes with lacrimation and stringy white discharge. • A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Management of and reporting procedure for adverse reactions	• 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: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • 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. • ***Anaphylaxis/Emergency Treatment at Derby and main Queens site:***

	• Call the crash team via switchboard • ***Anaphylaxis/Emergency treatment (at all other sites):*** ➢ Call 999 ➢ Summon help ➢ Maintain airway ➢ CPR • Follow trust resuscitation guidelines
Written information to be given to patient or carer	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.
Patient advice / follow up treatment	• May cause blurred vision, do not drive or use machinery until you can see clearly. • You should not wear your contact lenses during the course of treatment. • If you wear soft contact lenses do not wear them during treatment and for at least 24 hours after you have finished the eye ointment • The individual/carer should be advised to seek medical advice in the event of an adverse reaction. • Verbal advice on why the drug has been given, and subsequent management of the condition being treated.
Records	• Medical record/notes (specify which notes and section e.g. specific pathway) 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 • 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

Key references	• *Electronic Medicines Compendium* Chloramphenicol Eye Drops BP 0.5% W/V - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk), Chloramphenicol 1.0% w/w Antibiotic Eye Ointment - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) • *Electronic BNF https://bnf.nice.org.uk/* • *NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2* • *https://medusa.wales.nhs.uk*

7. Registered health professional authorisation sheet

PGD Name [version]: Core – Chloramphenicol 1% Eye Ointment and 0.5% Eye Drops [v1]
PGD ref: UHDB184

Valid from 17/10/2022 Expiry date: 16/10/2025

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**

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.