



This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Supply of

Chloramphenicol 0.5% Eye Drops

for the Treatment of

Bacterial Conjunctivitis (from 1 to 23 months of age inclusive)

by Registered Pharmacists, as part of the

Doncaster Clinical Minor Ailments Service

Version Number 2.0

Change History	
Version and Date	Change details
1.0 April 2021	New PGD
1.1 Sept 2021	Additional information on saline wash
2.0 Mar 2024	PGD Reviewed Section 2. Clinical Condition or Situation to which this PGD Applies <ul style="list-style-type: none">• Child age – changed from 3 months to 1 month to 23 months• Valid informed consent from parent/guardian - added• Babies/infants under 1 months of age – exclusion changed• Red flags which indicate the need for urgent ophthalmological assessment /escalation include: - exclusion added• Clinical information should be sent to the patient's GP in accordance with local protocols – added Section 3. Description of Treatment <ul style="list-style-type: none">• Dose and frequency of administration -updated• Duration of treatment -updated• Storage Store eye drops in a refrigerator at a temperature between 2-8°C – updated

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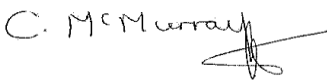

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	01/04/2024
Review date	01/01/2026
Expiry date:	31/03/2026

This PGD has been developed by the individuals named below. This PGD has been approved by the authorised signatories detailed in the Organisational Authorisations section of this document, on behalf of Doncaster Place.

Name	Designation
Chioma Nnamdi	Locality Lead Pharmacist, Medicines Optimisation Team
Faiza Ali	Locality Lead Pharmacist, Medicines Optimisation Team
Ning Wong	Locality Lead Pharmacist, Medicines Optimisation Team

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor Dr V V S Rao Kolusu	Locality lead GP and Prescribing lead Doncaster Place		28/03/2024
Senior pharmacist Charlotte McMurray	Chief Pharmacist NHS Doncaster Place		28/03/2024
Senior representative of professional group using the PGD			
Person signing on behalf of <u>authorising body</u> Dr V V S Rao Kolusu	Locality lead GP and Prescribing lead Doncaster Place		28/03/2024

GLOSSARY

PGD	Patient Group Direction
GPhC	General Pharmaceutical Council
OOH	Out of Hours Clinic

1. Characteristics of Staff

Qualifications and professional registration	Qualified pharmacist registered with the General Pharmaceutical Council (GPhC)
Initial training	Competent to work under Patient Group Directions, including satisfactory completion of training to assess patients and supply in accordance with this Patient Group Direction. Working as a community pharmacist and accredited to provide the Minor Ailments Service.
Competency assessment	CPPE Declaration of Competence Documents (DoCs). See Minor ailments (cppe.ac.uk) 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 senior individual responsible for authorising individuals to act under the PGD and further training provided as required.
Ongoing training and competency	Commitment to undertake training updates and revalidation according to the accreditation requirements of the commissioning organisation. Commitment to keep up to date with clinical developments in this area or changes to the recommendations for the medicine listed, as part of their Continuing Professional Development (CPD). Commitment to keep up to date Safeguarding training at a minimum of Level 2. The pharmacist must keep up to date with current legislation, including the Equality Act and Mental Capacity Act.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

2. Clinical Condition or Situation to which this PGD Applies

Clinical condition or situation to which this PGD applies	Bacterial conjunctivitis
Criteria for inclusion	<ul style="list-style-type: none"> • Valid informed consent from parent/guardian • Child aged 1 months to 23 months inclusive (under 2 years) presenting with a red, irritated/sticky eye indicative of bacterial conjunctivitis (muco-purulent) • Saline treatment has already been tried/ patient is unsuitable • Children over 2 years of age and adults should be advised to purchase chloramphenicol in accordance with self-care arrangements, if appropriate

Criteria for exclusion	<ul style="list-style-type: none"> • No consent obtained from the parent/carer of the infant • Babies/infants under 1 months of age • Patients 2 years of age and over • Any other current or recent infection of the eye, or any other known current or recent ocular condition • Any recent course of treatment for the same presentation (3-4 weeks) • Headache • Photophobia • Eye pain • Visual problems, including any change to visual acuity if this can be assessed • Known personal or family history of blood dyscrasias including aplastic anaemia • Viral conjunctivitis demonstrated by thin watery discharge • The pupil looks unusual • The eye looks cloudy • Known glaucoma • Dry eye syndrome • Eye inflammation associated with a rash on the scalp or face • Suspected foreign body in the eye • Any history of eye surgery or invasive treatment • Evidence of injury to the eye • Known hypersensitivity/allergy to chloramphenicol or any other excipient in the product • A history of bone marrow suppression during previous exposure to chloramphenicol • Red flags which indicate the need for urgent ophthalmological assessment /escalation include: <ul style="list-style-type: none"> - Signs of sepsis or meningitis (signs include acting confused, slurred speech or not making sense; blue, pale or blotchy skin, lips or tongue; a rash that does not fade when you roll a glass over it; difficulty breathing, breathlessness or breathing very fast) – call 999 or direct the patient to go to A&E - Severe eye pain, headache or photophobia — always consider serious systemic conditions such as meningitis in a person presenting with photophobia. - History of trauma (mechanical, chemical or ultraviolet) or possible foreign body. - Copious rapidly progressive discharge — may indicate gonococcal or chlamydia infection. o Infection with a herpes virus. - Soft contact lens use with corneal symptoms – photophobia and watering. - Reduced visual acuity.
Cautions including any relevant action to be taken	<ul style="list-style-type: none"> • Extra care should be taken with contact lens wearers because of complications - Note that it is highly unlikely that children under 2 years of age will wear contact lenses • Beware of risks of keratitis, corneal opacity or photophobia, signalling discomfort, or visual disturbances • Refer to Summary of Product Characteristics for the product supplied http://www.medicines.org.uk/emc/
Action to be taken if the patient is excluded	<ul style="list-style-type: none"> • Record reasons for exclusion in patient notes • Advise patient on alternative treatment if suitable • Refer to a prescriber such as the patient’s usual GP or NHS 111 if appropriate

Action to be taken if the patient or carer declines treatment	Refer to the patient's usual GP or NHS 111 if the patient is not able to see their GP, or is not registered with an NHS GP practice. Offer the patient details of relevant local services such as walk-in centres and OOH services if applicable.
	You must: <ul style="list-style-type: none"> • Document advice given • Advise patient on alternative treatment • Refer to a prescriber if appropriate
Arrangements for referral for medical advice	Supply the patient with a referral note to hand to the prescriber indicating the reasons for the referral. Clinical information should be sent to the patient's GP in accordance with local protocols

3. Description of Treatment

Name, strength & formulation of drug	Chloramphenicol 0.5% Eye Drops
Legal category	P or POM
Route / method of administration	Topical administration to the eye
Indicate any off-label use (if relevant)	The POM product must be supplied for use within its licenced posology and method of administration for the purpose of this PGD. The licence for the P product stipulates that patients should be 2 years and above. The directions in this PGD allow for the supply of this product to those stated in the inclusion criteria, subject to the professional judgement of the supplying pharmacist.
Dose and frequency of administration	Chloramphenicol 0.5% eye drops Instill one drop four times a day during waking hours and continue for 48 hours after infection has been eradicated
Duration of treatment	Maximum treatment period 5 days. If symptoms do not start to improve within 48 hours of starting treatment, the patient should seek further medical advice.
Quantity to be supplied	<ul style="list-style-type: none"> • 1 x 10ml bottle of chloramphenicol 0.5% w/v eye drops;
Storage	Offer the patient's parent/carer appropriate advice about the correct storage conditions. Store eye drops in a refrigerator at a temperature between 2-8°C Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Drug interactions	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	<p>The following side effects may be seen with chloramphenicol eye ointment:</p> <ul style="list-style-type: none"> • Local sensitivity reactions such as transient irritation, burning, stinging, and itching may occur • Angioedema, including facial oedema have been reported <p>Advise the patient that if they notice any adverse reactions, they must contact a pharmacist or their GP.</p> <p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website:</p>
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	www.medicines.org.uk
Management of and reporting procedure for adverse reactions	<ul style="list-style-type: none"> • 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 • Report via the pharmacy's policy for reporting adverse reactions
Written information to be given to patient or carer	<p>Give the marketing authorisation holder's patient information leaflet (PIL) with the product supplied every time.</p>
Patient advice / follow up treatment	<ul style="list-style-type: none"> • Discuss side effects and administration with the patient's parent/carer and provide a manufacturers patient information leaflet • Advise the parent/carer that the infection can spread, therefore need to wash hands after touching eyes and between applications if using the drops in both eyes • Advise the parent/carer about personal hygiene and not to share towels, face cloths, etc. • Advise the parent/carer not to touch the eye or lashes with the eye drops nozzle as this may contaminate the medicine • Advise parent/carer that their child's eyes may sting for a short time after using the eye ointment • Advise patient to discard eye ointment after completing the treatment • If patients are prescribed other eye ointments or drops, they should make the clinician aware that chloramphenicol is being used and to apply the new eye ointment first, wait 15 minutes, and then apply the chloramphenicol eye drops, unless the clinician states otherwise • Parents/carers must consult a GP if symptoms do not improve after 48 hours or sooner if symptoms worsen. This instruction must be included on the label • Advise the parent/carer that their child's vision may be temporarily impaired and to avoid activities that may require actions where impaired sight may introduce risks • Patient information is available on the NHS website https://www.nhs.uk

<p>Records</p>	<p>Record:</p> <ul style="list-style-type: none"> • That valid informed consent was given • 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) • Advice given, including advice given if excluded or declines treatment • Details of any adverse drug reactions and actions taken • That the medicine is supplied via a PGD <p>Records should be signed and dated (or a password controlled e-records).</p>
	<p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>

4. Key References

Key references	<ul style="list-style-type: none">• Electronic Medicines Compendium http://www.medicines.org.uk/• Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2• Common Conditions and Minor Ailments https://www.cppe.ac.uk/learningdocuments/pdfs/common_clinical_conditions_and_minor_ailments.pdf• CPPE Minor Ailments and Declaration of Competence https://www.cppe.ac.uk/gateway/minor• NHS Medicines Chloramphenicol https://www.nhs.uk/medicines/chloramphenicol/• Clinical Knowledge Summary Conjunctivitis-Infective https://cks.nice.org.uk/conjunctivitis-infective
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5. Registered Pharmacist Authorisation Sheet

Before signing this PGD, check that the document has had the necessary authorisations in Section 1. Without these, this PGD is not lawfully valid.

Registered Pharmacist

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

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