



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 Eye Ointment 1.0%**

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

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

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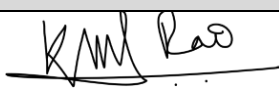
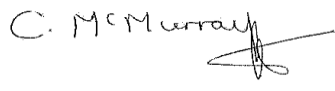

## PGD DEVELOPMENT GROUP

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 CCG.

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

<b>Qualifications and professional registration</b>	Qualified pharmacist registered with the General Pharmaceutical Council (GPhC)
<b>Initial training</b>	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.
<b>Competency assessment</b>	CPPE Declaration of Competence Documents (DoCs). See <a href="http://cppe.ac.uk">Minor ailments (cppe.ac.uk)</a>  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>  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.
<b>Ongoing training and competency</b>	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.
<b>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.</b>	

## 2. Clinical Condition or Situation to which this PGD Applies

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

<b>Criteria for exclusion</b>	<ul style="list-style-type: none"> <li>• No consent obtained from the parent/carer of the infant</li> <li>• Babies/infants under 1 months of age</li> <li>• Patients 2 years of age and over</li> <li>• Any other current or recent infection of the eye, or any other known current or recent ocular condition</li> <li>• Any recent course of treatment for the same presentation (3-4 weeks)</li> <li>• Headache</li> <li>• Photophobia</li> <li>• Eye pain</li> <li>• Visual problems, including any change to visual acuity if this can be assessed</li> <li>• Known personal or family history of blood dyscrasias including aplastic anaemia</li> <li>• Viral conjunctivitis demonstrated by thin watery discharge</li> <li>• The pupil looks unusual</li> <li>• The eye looks cloudy</li> <li>• Known glaucoma</li> <li>• Dry eye syndrome</li> <li>• Eye inflammation associated with a rash on the scalp or face</li> <li>• Suspected foreign body in the eye</li> <li>• Any history of eye surgery or invasive treatment</li> <li>• Evidence of injury to the eye</li> <li>• Known hypersensitivity/allergy to chloramphenicol or any other excipient in the product</li> <li>• A history of bone marrow suppression during previous exposure to chloramphenicol</li> <li>• Red flags which indicate the need for urgent ophthalmological assessment /escalation include: <ul style="list-style-type: none"> <li>- 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 of breathing very fast) – call 999 or direct the patient to go to A&amp;E</li> <li>- Severe eye pain, headache or photophobia — always consider serious systemic conditions such as meningitis in a person presenting with photophobia.</li> <li>- History of trauma (mechanical, chemical or ultraviolet) or possible foreign body.</li> <li>- Copious rapidly progressive discharge — may indicate gonococcal or chlamydia infection. o Infection with a herpes virus.</li> <li>- Soft contact lens use with corneal symptoms – photophobia and watering.</li> <li>- Reduced visual acuity.</li> </ul> </li> </ul>
<b>Cautions including any relevant action to be taken</b>	<ul style="list-style-type: none"> <li>• 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</li> <li>• Beware of risks of keratitis, corneal opacity or photophobia, signalling discomfort, or visual disturbances</li> <li>• Refer to Summary of Product Characteristics for the product supplied <a href="http://www.medicines.org.uk/emc/">http://www.medicines.org.uk/emc/</a></li> </ul>
<b>Action to be taken if the patient is excluded</b>	<ul style="list-style-type: none"> <li>• Record reasons for exclusion in patient notes</li> <li>• Advise patient on alternative treatment if suitable</li> <li>• Refer to a prescriber such as the patient’s usual GP or NHS 111 if appropriate</li> </ul>

<b>Action to be taken if the patient or carer declines treatment</b>	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"> <li>• Document advice given</li> <li>• Advise patient on alternative treatment</li> <li>• Refer to a prescriber if appropriate</li> </ul>
<b>Arrangements for referral for medical advice</b>	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

<b>Name, strength &amp; formulation of drug</b>	Chloramphenicol 1% Eye Ointment
<b>Legal category</b>	P or POM
<b>Route / method of administration</b>	Topical administration to the eye
<b>Indicate any off-label use (if relevant)</b>	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.
<b>Dose and frequency of administration</b>	Apply small amount (approximately 1cm) of ointment into the space between the lower eye lid four times a day <b>and continue for 48 hours after infection has been eradicated</b>
<b>Duration of treatment</b>	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.
<b>Quantity to be supplied</b>	<ul style="list-style-type: none"> <li>• 1 x 4g tube of chloramphenicol 1.0% w/w eye ointment; or</li> </ul> Increasing to 2 if bilateral
<b>Storage</b>	Chloramphenicol 1% eye ointment is stored in ambient storage conditions, usually within the range of 8-25°C. Offer the patient's parent/carer appropriate advice about the correct storage conditions.  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: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a>
<b>Drug interactions</b>	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a>

<b>Identification &amp; management of adverse reactions</b>	<p>The following side effects may be seen with chloramphenicol eye ointment:</p> <ul style="list-style-type: none"> <li>• Local sensitivity reactions such as transient irritation, burning, stinging, and itching may occur</li> <li>• Angioedema, including facial oedema have been reported</li> </ul> <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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	<a href="http://www.medicines.org.uk">www.medicines.org.uk</a>
<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>• Report via the pharmacy's policy for reporting adverse reactions</li> </ul>
<b>Written information to be given to patient or carer</b>	<p>Give the marketing authorisation holder's patient information leaflet (PIL) with the product supplied every time.</p>
<b>Patient advice / follow up treatment</b>	<ul style="list-style-type: none"> <li>• Discuss side effects and administration with the patient's parent/carer and provide a manufacturers patient information leaflet</li> <li>• Advise the parent/carer that the infection can spread, therefore need to wash hands after touching eyes and between applications if using the ointment in both eyes</li> <li>• Advise the parent/carer about personal hygiene and not to share towels, face cloths, etc.</li> <li>• Advise the parent/carer not to touch the eye or lashes with the eye ointment nozzle as this may contaminate the medicine</li> <li>• Advise parent/carer that their child's eyes may sting for a short time after using the eye ointment</li> <li>• Advise patient to discard eye ointment after completing the treatment</li> <li>• 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 ointment, unless the clinician states otherwise</li> <li>• Parents/carers must consult a GP if symptoms do not improve after 48 hours days or sooner if symptoms worsen. This instruction must be included on the label</li> <li>• 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</li> <li>• Patient information is available on the NHS website <a href="https://www.nhs.uk">https://www.nhs.uk</a></li> </ul>

<b>Records</b>	<p>Record:</p> <ul style="list-style-type: none"> <li>• That valid informed consent was given</li> <li>• Name of individual, address, date of birth and GP with whom the individual is registered (if relevant)</li> <li>• Name of registered health professional</li> <li>• Name of medication supplied/administered</li> <li>• Date of supply/administration</li> <li>• Dose, form and route of supply/administration</li> <li>• Quantity supplied/administered</li> <li>• Batch number and expiry date (if applicable)</li> <li>• Advice given, including advice given if excluded or declines treatment</li> <li>• Details of any adverse drug reactions and actions taken</li> <li>• That the medicine is supplied via a PGD</li> </ul> <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

<b>Key references</b>	<ul style="list-style-type: none"> <li>• Electronic Medicines Compendium <a href="http://www.medicines.org.uk/">http://www.medicines.org.uk/</a></li> <li>• Electronic BNF <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a> • 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> <li>• Common Conditions and Minor Ailments <a href="https://www.cppe.ac.uk/learningdocuments/pdfs/common_clinical_conditions_and_minor_ailments.pdf">https://www.cppe.ac.uk/learningdocuments/pdfs/common_clinical_conditions_and_minor_ailments.pdf</a></li> <li>• CPPE Minor Ailments and Declaration of Competence <a href="https://www.cppe.ac.uk/gateway/minor">https://www.cppe.ac.uk/gateway/minor</a></li> <li>• NHS Medicines Chloramphenicol <a href="https://www.nhs.uk/medicines/chloramphenicol/">https://www.nhs.uk/medicines/chloramphenicol/</a></li> <li>• Clinical Knowledge Summary Conjunctivitis-Infective <a href="https://cks.nice.org.uk/conjunctivitis-infective">https://cks.nice.org.uk/conjunctivitis-infective</a></li> </ul>
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