NHS
Cornwall and Isles of Scilly

Patient group direction for the supply of chloramphenicol 0.5% eye drops by community pharmacists for the management of bacterial conjunctivitis

Documentation details

Reference no: PGD01
Version no: 2
Valid from: April 2023
Review date: December 2024
Expiry date: March 2025

Change history

Version number	Date	Details
1		New template
1.1	30 July 2021	Amendment following Medicines and Healthcare products Regulatory Agency (MHRA) drug safety update: Chloramphenicol eye drops containing borax or boric acid buffers: use in children younger than 2 years (published 7 July 2021) New accessible template
2		Transfer to ICB stationery Renumber to PGD01 Review of PGD

Patient group direction development

Date template comes into effect: April 2023
Version no: 2
Valid from: April 2023
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Expiry date: March 2025

Patient group direction working group

This patient group direction (PGD) was developed by a working group involving pharmacists from NHS Cornwall and Isles of Scilly integrated care board (CIOS ICB), GP clinical leads from CIOS ICB and microbiology.

Name and role	Job title	Organisation
Chris Burgin Pharmacist and lead reviewer	Pharmaceutical advisor	Cornwall and Isles of Scilly ICB
Anne Jones Pharmacist	Pharmaceutical advisor	Cornwall and Isles of Scilly ICB
Medicines optimisation programme board (MOPB), reviewers, February 2023		
Dr Jim Huddy, GP	General practitioner	Cornwall and Isles of Scilly ICB
Mike Wilcock, pharmacist	Head of prescribing support unit	Royal Cornwall Hospitals NHS Trust (RCHT) and Cornwall and Isles of Scilly ICB
Philip Yelling	Consultant	Cornwall and Isles of Scilly Local Pharmaceutical Committee

Based on the previous version commissioned by NHS Kernow Clinical Commissioning Group and authored by Fiona Lee, with contributions from Georgina Praed, Amanda Pell and Paige Trethewey.

Organisational authorisations

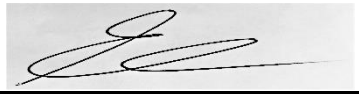
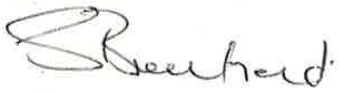
The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

CIOS ICB authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services: Community pharmacies contracted to provide the CIOS ICB community pharmacy PGD service for minor ailments.

Limitations to authorisation: None.

Approved by	Name	Date of email approval
CIOS ICB interim head of prescribing and medicines optimisation	Marco Motta 	28 February 2023
CIOS ICB chief medical officer	Chris Reid	Approved by email 26 February 2023
CIOS ICB chief nursing officer	Susan Bracefield 	7 March 2023

Local enquiries regarding the use of this PGD may be directed to ciosicb.prescribing@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD. Alternative authorisation sheets and templates may be used where appropriate in accordance with local policy.

Characteristics of staff

Qualifications and professional registration

Registered professional with one of the following bodies:

- pharmacists registered with the General Pharmaceutical Council (GPhC)

Initial training

- Must be authorised by name as an approved practitioner under the current terms of this PGD before working to it.
- Has undertaken appropriate training and been assessed and declared competent to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD.
- Must be competent in the use of PGDs (see NICE competency framework for health professionals using PGDs).
- Must have access to the PGD and associated online resources.

Competency assessment

All pharmacists operating under this PGD are required to complete a declaration of competence for minor ailments via the Centre Pharmacy Postgraduate Education (CPPE) website and complete the declaration of competence on PharmOutcomes.

Staff operating under this PGD are encouraged to review their competency using the NICE competency framework for health professionals using PGDs.

Staff operating under this PGD are encouraged to attend specific commissioning organised training events on minor ailments and complete the CPPE common clinical conditions and minor ailments and e-assessment.

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.

Ongoing training and competency

Practitioners must ensure they are up to date with relevant issues and clinical skills relating to the management of impetigo, with evidence of appropriate continued professional development (CPD).

Pharmacists will be required to complete an annual declaration of competence via the CPPE website and PharmOutcomes.

The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.

Clinical condition or situation to which this PGD applies

Condition or situation: Treatment of bacterial conjunctivitis

Criteria for inclusion

Patients over the age of 1 year and under the age of 2 presenting with bacterial conjunctivitis in one or both eyes. Eye(s) is red, feels sore or gritty and has a sticky discharge.
Parental consent must be obtained before offering to treat a patient under 16 years of age who is not considered competent to consent to treatment

Criteria for exclusion

- No consent obtained
- Babies under the age of 1 year
- Adults and children aged 2 years and older
- Allergy to any component of chloramphenicol 0.5% eye drops
- Patients who have experienced myelosuppression during previous exposure to chloramphenicol
- Patients with a family history of blood dyscrasias including aplastic anaemia.
- Concurrent myelotoxic drugs
- Foreign body in eye.
- Painful red eye or pain felt on touching closed eye
- Orbital cellulitis
- Blurred, double, or loss of vision
- Photophobia
- Eye surgery or laser treatment in the last 6 months
- Recent eye injury
- Patient presents with systemic symptoms
- Eye inflammation associated with a rash on the scalp or face

- Previous conjunctivitis in recent past
- Glaucoma
- Dry eye syndrome
- Eye injury
- The eye looks cloudy
- The pupil looks unusual

Cautions including any relevant action to be taken
Prolonged use of chloramphenicol eye drops should be avoided as it may increase the likelihood of sensitisation and emergence of resistant organisms, including fungi.

Action to be taken if the patient is excluded
- Record reasons for exclusion and any action(s) taken.
- Advise patient on alternative treatment.
- Refer to a prescriber if appropriate (for example emergency department, GP, or NHS 111 or out of hours (OOH) service).
- Give safety-netting advice.

Action to be taken if the patient or carer declines treatment
- Document advice given and the decision reached.
- Advise patient on alternative treatment if appropriate.
- Refer to a prescriber if appropriate.
- Give safety-netting advice.

Arrangements for referral for medical advice
Advise people with bacterial conjunctivitis, and their parents or carers if appropriate, to seek medical help if symptoms worsen at any time, or symptoms persist after completing a course of treatment.

Description of treatment

Name, strength and formulation of drug
Chloramphenicol 0.5% eye drops.

Legal category
Pharmacy only medicines (P).

Route and method of administration
Topical (ocular use only).

Indicate any off-label use (if relevant)
The medicine is being used outside the terms of the marketing authorisation. Inform the patient or their carer that the use is off-label, in line with General Medical Council guidance on prescribing unlicensed medicines.
Inform the patient that whilst the patient information leaflet (PIL) included in the product packaging may refer to the product being unsuitable for use in children younger than 2 years of age that the MHRA has concluded that the benefits of chloramphenicol eye drops containing borax or boric acid outweigh the potential risks for children, including those aged 0 to 2 years.
Please see MHRA drug safety update: Chloramphenicol eye drops containing borax or boric acid buffers: use in children younger than 2 years (published 7 July 2021) for full details.

Dose and frequency of administration
Put one drop into the affected eye(s) every 2 hours for the first 48 hours and 4 hourly thereafter.
To be used during waking hours only.

Duration of treatment
5 days.
Treatment should be continued for at least 48 hours after eye appears normal.

Quantity to be supplied
10mls

Storage
Stock must be stored in conditions in line with the summary of product characteristics (SPC).
Store in a refrigerator at a temperature between 2°C and 8°C.

Drug interactions
The concomitant administration of Chloramphenicol with other drugs liable to depress bone marrow function should be avoided as per the SPC

Identification and management of adverse reactions
Adverse effects are usually minor, such as transient stinging or a burning sensation in the eye.
Hypersensitivity reactions including angioedema, anaphylaxis, urticaria, fever, vesicular and maculopapular dermatitis as per the SPC. Treatment must be discontinued immediately in such cases.
Bone marrow depression, including the idiosyncratic type of irreversible and fatal aplastic anaemia that is recognised to occur with systemic therapy, has been reported in association with topical administration of chloramphenicol as per the SPC.

Management of and reporting procedure for adverse reactions
- Healthcare professionals and patients or carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme .
- Record all adverse drug reactions (ADRs) in the patient's medical record (and inform the patient's GP).
- Report via organisation incident policy.

Written information to be given to patient or carer
The marketing authorisation holder's patient information leaflet provided with the product if treatment is to be supplied and advise patient to read the leaflet.

Patient advice and follow up treatment
- Parents should be advised that conjunctivitis usually clears by itself without treatment
- Wash your hands with soap and hot water
- In small children and babies, place the drop into the inner corner of the eye. This is easier with the eye open, but the liquid will still drain on to the eye even with a closed eye if you can hold your child's head still for a few seconds.
- After giving eye drops, your child should keep their eye closed for as long as they can (5 seconds if possible) so that the eye drop doesn't spill out.

- If you think the drop didn't go into the eye, you can repeat the process but do not try more than twice.
- Try to avoid the tip of the tube touching any part of your child's eye, if possible.
- Adverse effects are usually minor, such as transient stinging or a burning sensation in the eye
- Use the eye drops for five days and then discard.
- Prolonged use of chloramphenicol eye drops should be avoided as it may increase the likelihood of sensitisation and emergence of resistant organisms, including fungi.
- Bathe eyes with freshly boiled warm water if sticky in the mornings. Use fresh cotton wool pad each time.
- If an allergic reaction occurs from using the eye drops, stop and seek medical advice.
- Have a separate flannel and towel to prevent spreading the infection to other members of the family.
- Do not share the treatment with anyone else.

Records

- Completion of PGD checklist on PharmOutcomes.
- Completion of patient medication record.
- Label the pack being supplied appropriately:
    - dose, form and route of supply or administration
    - quantity supplied or administered
    - supplied via PGD
- Record details of any adverse drug reactions and actions taken.
- Referral arrangements (including self-care).
- Batch number and expiry date (if applicable).
- Completion of consent form and completion of the audit claim on PharmOutcomes.
- Records should be signed and dated (or a password controlled e-records).
- All records should be clear, legible and contemporaneous.
- A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

Audit trail

- PMR entry.
- Patient's GP should be notified using the notification form on PharmOutcomes within 48 hours of supply for inclusion in the patients notes.

Key references

- NICE [NG153] impetigo guidelines
- nhs.uk impetigo advice
- CIOS ICB management of infection guidelines
- Summary of Product Characteristics
- British Association of Dermatologists leaflet
- NICE PGD medicines practice guideline [MPG2]
- Specialist Pharmacy website
- Regulatory Agency (MHRA) drug safety update: Chloramphenicol eye drops containing borax or boric acid buffers: use in children younger than 2 years (published 7 July 2021)

Registered health professional authorisation sheet

PGD: Supply of chloramphenicol 0.5% eye drops by community pharmacists in the management of bacterial conjunctivitis.

Valid from: 1 April 2023
Expiry: 31 March 2025

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Authorisation

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 PGD and that I am willing and competent to work to it within my professional code of conduct.

Name	Designation	Signature	Date

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.