

This Patient Group Direction (PGD) must only be used by registered pharmacists 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

for the supply of

Chloramphenicol Eye Drops 0.5%

For Children aged 3 months to 2 years

by registered pharmacists for the

Treatment of Superficial Eye Infections

under the Wirral Clinical Commissioning Group Minor Ailments Service

Version number: 5

Important Information

From October 2021, this PGD has been reinstated for use within community pharmacies as part of the CCG Think pharmacy scheme.

In March 2021, the Think Pharmacy Chloramphenicol Eye Drops 0.5% PGD was suspended by NHS Wirral CCG due to national safety concerns.

On 7th July 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) published information confirming that Chloramphenicol eye drops can be safely administered to children aged 0 to 2 years where antibiotic eye drop treatment is indicated – please see summary below:

Chloramphenicol eye drops containing borax or boric acid buffers: use in children younger than 2 years

Following a review of the available toxicological data and a calculation of daily exposure to boron from a typical dosing regimen, we have concluded that the balance between the benefits and risks of chloramphenicol eye drops containing borax or boric acid remains positive for children aged 0 to 2 years. Chloramphenicol eye drops can be safely administered to children aged 0 to 2 years where antibiotic eye drop treatment is indicated.

Further information available at: <https://www.gov.uk/drug-safety-update/chloramphenicol-eye-drops-containing-borax-or-boric-acid-buffers-use-in-children-younger-than-2-years>

Change history:

Version number	Change details	Date
1.0	Original Document developed with the PGD Development and review group	May 2015
2.0	Review and Amendments by the PGD Development and review group	March 2016
2.1	Update in line with NHS Wirral CCG Self-care policy	February 2017
3.0	Review and Amendments by the PGD Development and review group	March 2019
3.1	Review in line with latest guidance. Updated inclusion criteria, exclusion criteria and cautions. Updated action to be taken if patient declines and reworded patient information section from point of view offering advice to parent/carer.	January 2021

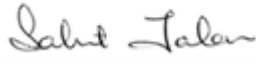

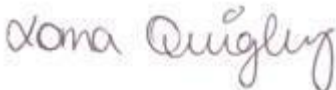
Valid from: October 2021
Expiry March 2023

4.0	PGD suspended due to national patient safety concerns relating to boron/boric acid.	March 2021
4.1	Addition of new MHRA guidance, including dosing and parent/carer information - published 07/07/2021.	July 2021
5.0	Review and Amendments by the PGD Development and review group	Sept 2021

PGD development

Name	Job title and organisation
Lead author Nicola Bradley Updated by Lynne Sahlman and Abigail Cowan Updated by Victoria Vincent (January 2021) MHRA Guidance added by Abigail Cowan (July 2021)	Medicines Management Pharmacists Midlands and Lancashire Commissioning Support Unit (MLCSU)
Lead doctor Dr Saket Jalan	Clinical Lead for Urgent Care and Meds Management
Lead pharmacist Robert Hebdon	Senior Medicines Optimisation Pharmacist, MLCSU
Representative of other professional group using PGD Adam Irvine	Community Pharmacy Cheshire and Wirral (CPCW)
Other members of the PGD working group: Richard Crockford, NHS Wirral CCG	

PGD Authorisation

Name	Job title and organisation	Signature	Date
Senior doctor Dr S Jalan	Clinical Lead for Urgent Care and Medicines Management, NHS Wirral CCG		28/09/2021
Senior pharmacist Robert Hebdon	Senior Medicines Optimisation Lead, MLCSU		28/09/2021
Person signing on behalf of Wirral CCG Lorna Quigley	Director of Quality and Safety NHS Wirral CCG		28/09/2021

PGD adoption by the provider

Name	Job title and organisation	Signature	Date
Signatures to be determined locally, if relevant			

Training and competency of registered pharmacist

	Requirements of registered pharmacists working under the PGD
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 administer/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)
Ongoing training and competency	Commitment to continuing updating and re-validation according to the accreditation requirements of the commissioning organization. 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 Continual Professional Development.

Clinical condition

Clinical condition or situation to which this PGD applies	Superficial Eye Infections
Inclusion criteria	<ul style="list-style-type: none"> • Child aged 3 months and under 2 years presenting with a red, irritated/sticky eye including the following situations: <ul style="list-style-type: none"> ○ Bacterial conjunctivitis (muco-purulent) ○ External and internal stye ○ Parent/carer agrees to treatment under this PGD. • Self-care has been tried and not successful. • Self-care: bathe or clean eyelids with cotton wool dipped in sterile saline or boiled (cooled) water, to remove crusting. Explain red flags for urgent review and advise the person to seek further help if symptoms persist beyond 7 days. • Pharmacist must see the patient.
Exclusion criteria	<ul style="list-style-type: none"> • Self-care not been tried first. • No consent obtained. • Babies/infants under 3 months of age. • Patient is not present in the pharmacy • Severe infections, including evidence of pre-septal cellulitis such as, eyelid oedema in the absence of orbital signs such as gaze restriction and proptosis • Any recent course of treatment (3-4 weeks) • Current use of any other eye drops or eye treatment • Headache • Photophobia • Eye pain • Corneal abrasion/ulcer • 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 • Glaucoma • Dry eye syndrome • Eye inflammation associated with a rash on the scalp or face • Suspected foreign body in the eye • Eye surgery or laser treatment in the last 6 months • 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

Cautions (including any relevant action to be taken)	<ul style="list-style-type: none"> Refer to Summary of Product Characteristics http://www.medicines.org.uk/emc/
Arrangements for referral for medical advice	<ul style="list-style-type: none"> Supply the patient with a referral note to hand to the GP indicating the reasons for the referral
Action to be taken if patient excluded	<ul style="list-style-type: none"> Refer to GP practice Clearly record the decision on the patient's consultation proforma including any advice given and action taken.

Details of the medicine

Name, form, and strength of medicine	Chloramphenicol 0.5% Eye Drops
Legal category	P (maximum pack size 10ml)
Indicate any off-label use (if relevant)	N/A
Route/method of administration	Topical
Dose and frequency	<p>During awake hours instill one drop 3 to 4 times a day, to the affected eye(s). As per MHRA guidance this would result in a daily exposure well below the safety limit for children aged 0 to 2 years.</p> <p>Continue treatment for 48 hours after healing.</p> <p>Maximum duration of treatment 5 days.</p>
Quantity to be administered and/or supplied	Supply 1 x 10ml bottle for one treatment episode
Maximum or minimum treatment period	Maximum treatment period of five days.
Adverse effects	<p>Local sensitivity reactions such as transient irritation, burning, stinging, and itching may occur.</p> <p>Refer to SPC or current BNF for full details</p>
Records to be kept	<p>The following will be recorded in the patient's consultation proforma:</p> <ul style="list-style-type: none"> Advice given to parent or carer Patient's name, address, date of birth and GP Date and time of supply The batch number and expiry date The name of the person supplying the medicine

Patient information

<p>Verbal/written advice to be given to parent/carer on behalf of the patient</p>	<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 (personal hygiene) and not to share towels etc. • Advise parent/carer that they must not touch the eye or lashes with the eye drops nozzle as this may contaminate the medicine. • Advise parent/carer that the child's eyes may sting for a short time after using the eye drops. • Advise parent/carer to discard eye drops after completing the treatment. • Consult the GP if symptoms do not improve after 3 days or sooner if symptoms worsen. This instruction must be included on the label. • Patient information is available on the NHS website at; https://www.nhs.uk/ • MHRA Guidance (July 2021) - advice for healthcare professionals to provide to parents and carers <ul style="list-style-type: none"> • eye infections (conjunctivitis) are very common in babies and infants and it is important they are treated properly • chloramphenicol eye drops are an important medicine for treating bacterial eye infections in children and have been used safely for many years • some eye drops contain borax or boric acid, which are sources of boron – these ingredients are included as buffers to make sure the medicine is not too acidic or alkaline and is comfortable when administered to the eye • although concerns have been raised about boron and a possible effect on future fertility, these products can be safely given to children younger than 2 years as advised by a doctor or other prescriber. • experts have advised that the amount of liquid that can be absorbed through the eyes of young children and the way these products are prescribed mean that the daily exposure to children would be well below the calculated safety limits. • https://www.gov.uk/drug-safety-update/chloramphenicol-eye-drops-containing-borax-or-boric-acid-buffers-use-in-children-younger-than-2-years
<p>Follow-up advice to be given to patient or carer</p>	<p>Contact GP if no improvement of symptoms after 3 days or sooner if symptoms worsen</p>

Valid from: October 2021
Expiry March 2023

Appendices

Appendix A Key references

1. Clinical Knowledge Summaries Guideline at <https://cks.nice.org.uk/topics/conjunctivitis-infective/> last updated April 2018 (Accessed January 2021)
2. Summary Product Characteristic (SPC) at (Accessed January 2021)
3. NHS Website - <https://www.nhs.uk/medicines/chloramphenicol/> (Accessed January 2021)
4. Pan Mersey
https://www.panmerseyapc.nhs.uk/media/2032/eye_201806_ag06_v0100.pdf
(Accessed January 2021)
5. BNFc <https://bnfc.nice.org.uk/drug/chloramphenicol.html> (Accessed January 2021)
6. MHRA - <https://www.gov.uk/drug-safety-update/chloramphenicol-eye-drops-containing-borax-or-boric-acid-buffers-use-in-children-younger-than-2-years>
(published 7th July 2021)

Appendix B Health professionals' agreement to practice

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD.

Name of pharmacist	Signature	Senior representative authorising pharmacist	Date