Moorfields Eye Hospital NHS
NHS Foundation Trust

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

for the **supply** of

cyclopentolate 0.5%, or cyclopentolate 1%

or atropine 1% eye drops

by registered **orthoptists** to

parents, legal guardians or carers of paediatric patients who require:

either

refraction

or

fundoscopy with refraction

in Moorfields Eye Hospital NHS Foundation Trust

PGD Code	PGD057
Version	1.1
Status	Final

Version history

Version	Date	Brief summary of change	Author
1.0	Jan 2019	New PGD for the supply of dilating / cycloplegia drops to parents/guardians/carers to instil at home prior to attending the out-patient clinic appointment for refraction or fundoscopy with refraction	Kelly MacKenzie
1.1	April 2019	New appendix for over-labels of supplied medicines	Kelly MacKenzie

Contact for information on this document	Kelly MacKenzie (Orthoptist)
PGD Author(s)	Kelly MacKenzie (Orthoptist)
PGD Owner(s)	Paediatric Service
Accountable Director(s)	Jo Hancox, Service Director
Date of issue	February 2019
Date of review	February 2022
Responsible Committee Group for final approval	Drugs and Therapeutics and Medicines Management Committee (DTMMC)
Audience	This document is applicable to all authorised staff who administer or supply medicines via the Patient Group Direction (PGD)
Dissemination and implementation	Notification of a substantive revision or minor amendment to this PGD will be communicated via the staff e-bulletin, which is published by the Marketing and Communications team on a weekly basis.

Contents

PGD Development Authors

Name Print	**Full job title (print)**	**Signature**	**Date**
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PGD Trust Authorisation

Name	**Job title**	**Signature**	**Date**
NICK STROUTHIDIS	Medical Director	N. STROUTHIDIS	05/08/19
STUART SEMPLE	Chief Pharmacist	S. SEMPLE	06/08/19
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Groups/Committees involved in assessing this PGD

Group committee	**Service/organisation**	**Date discussed**
Directorate Service meeting	Paediatric Service	22 Jan 2019
Non-Medical Supply of Medicines Group	Moorfields Eye Hospital	24 Jan 2019
DTMMC	Moorfields Eye Hospital	29 April 2019

Training and competency of registered health professionals

Orthoptist	
Qualifications and professional registration	Registered Orthoptist : Authorised orthoptist with degree or diploma in orthoptics
Additional requirements	Be authorised by name as an approved practitioner under the current terms and version of this PGD before working to it. Be working at Band 5 and above Have successful and documented completion of this PGDs competency assessment – The line manager must have assessed the practitioner as professionally competent in all aspects of this process (see NICE Competency framework)
Ongoing training and competency	Have access to the PGD and associated online resources. Fulfil any additional requirements defined by local policy. Have successful and documented completion of Medicines Awareness training Actively partaking in CPD and annual Individual Performance Review

Named health professional authorised to supply and/or administer medications under the PGD must meet the above criteria.

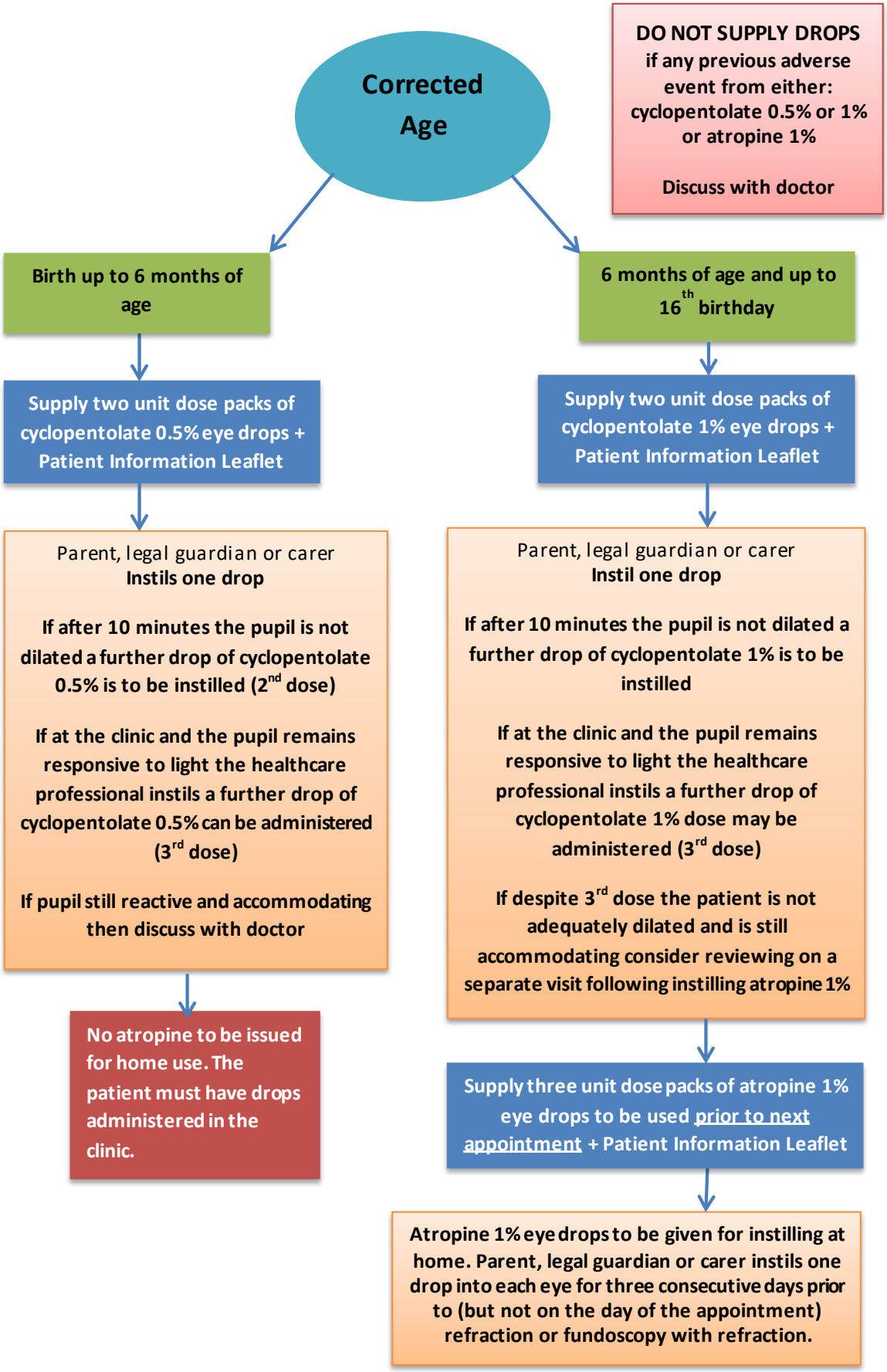
Practitioners not listed are not authorised to practice under this PGD.

An up to date list and signatures of registered practitioners who are authorised to practice under this PGD is kept in the **Paediatric Department** and **Orthoptic Department** by the **Head of Department**

Summary sheet for Patient Group Direction

Objective of PGD	To allow orthoptists to supply drops to the parents, legal guardians or carers to dilate the pupils and / or produce cycloplegia in their child prior to attending a Moorfields Eye Hospital NHS Foundation Trust. The eye drops should be instilled prior to refraction or fundal examination with refraction. Verbal and written instructions will be provided.
Characteristics of staff authorised to take responsibility for the administration of medicines under this protocol include:	• Orthoptist
Supply/administration	• Supply only
Medicine details	• Cyclopentolate 0.5% single unit does eye drops • Cyclopentolate 1% single unit dose eye drops • Atropine 1% single unit dose eye drops
PGD should be used in conjunction with	• Summary of Product Characteristics • The corresponding practitioner protocol • The Human Medicines Regulations 2012 • Administration of Medicines policy (Moorfields) • Medicines Policy (Moorfields) • Patient Group Directives policy (Moorfields)

Instructions for Refraction with or without fundoscopy



Clinical condition

Clinical condition or situation to which this PGD applies	This PGD applies to paediatric patients in the paediatric service attending Moorfields Eye Hospital NHS Foundation Trust who require dilation and /or cycloplegia for: • refraction • fundoscopy with refraction

Inclusion criteria	• All paediatric patients from birth up to 16th birthday who require any of the following examinations:
	  • refraction
	  • fundoscopy with refraction
	• All patients need to have had a vision assessment by a Moorfields orthoptist/optometrist within the proceeding two months
	• Patients attending the following Moorfields eye centres:
	  o City Road Campus
	  o Hackney Ark (at Homerton)
	  o Potters Bar Community Hospital
	  o Darent Valley Hospital
	  o Sir Ludwig Guttman Health & Wellbeing Centre
	  o Ealing Hospital
	  o Northwick Park Hospital
	  o St. George's Hospital
	  o Croydon University Hospital
	  o Purley War Memorial Hospital
	  o Parkway Health Centre (New Addington)
	  o Sanderstead Health Centre
	• Patients must live within approximately one hour (not more than an hour and a half) travelling distance to their appointment location.

Exclusion criteria	**Description of those patients excluded from treatment under this direction:** • Patient, parent, carer or legal guardian refuses consent • Patients with narrow angle glaucoma (unless previously treated with iridectomy or iridotomy) and those where the filtration angle is narrow. Mydriasis in these patients may precipitate acute angle closure • Pregnant or lactating females – safety for use in pregnancy and lactation has not been established **Cyclopentolate 0.5% and 1% exclusions:** • Known hypersensitivity to cyclopentolate or any component of the preparation. **Atropine 1% exclusions:**

	• Known hypersensitivity to atropine or any component of the preparation • Patients with known narrow angle glaucoma (unless previously treated with iridectomy or iridotomy and those where the filtration angle is narrow). Mydriasis in these patients may precipitate acute angle closure • Patients with Down's syndrome • Patients with known history of cardiac disorders
Action to be taken if patient excluded	For **ALL** patients excluded from this PGD, the health care professional must obtain an individual prescription or some other form of instruction from the ophthalmologist e.g. entry in patient's notes. In the absence of a doctor, approach an optometrist with prescribing rights to write an individual prescription in the notes. If the patient/parent/legal guardian does not wish to receive treatment in accordance with this Patient Group Direction, he/she must be referred to an ophthalmologist. The reason for referral must be documented in the patient's notes
Action to be taken if patient declines treatment	Document in patient notes, inform and discuss with consultant or fellow in charge.
Arrangements for referral for medical advice	Any child with a suspected adverse reaction must be seen by a paediatrician and/or an ophthalmologist. All suspected adverse drug reactions must be reported and recorded in patient's notes to avoid repeated application. Parents/guardian or carer should contact the nearest A&E immediately (if they have left the premises) if the child experiences any of the following symptoms; swelling and/or redness of eyelids or conjunctivae or watering of the eyes, gritty or foreign body sensation. These symptoms may indicate a possible allergy. Any effects on the circulatory system, causing increased blood pressure, palpitations, fast heartbeats (tachycardia) and other heart irregularities (extrasystoles and cardiac arrhythmias). Should this occur, the patient should seek emergency help immediately. In extremely rare cases these medicines may cause an acute attack of angle closure glaucoma. Symptoms may include ocular pain, visual blurring, coloured halos around lights and nausea or vomiting. Should this occur the patient should seek emergency help immediately.

Details of the medicine

Name, form and strength of medicine	Legal category
Cyclopentolate 0.5% single unit dose eye drops	POM
Cylopentolate 1% single unit dose eye drops	POM
Atropine 1% single unit dose eye drops	POM

POM=Prescription Only Medicine

These are not a black triangle medicines and do not require intensive monitoring by the Medicines and Healthcare products Regulatory Agency (MHRA).

Algorithms or flow charts of how these medicines are used along with the patient pathway can be found on page 7

The decision to administer or supply any medication rests with the individual registered practitioner. The registered practitioner must adhere to the Trust PGD Policy and the applicable clinical guidelines.

No prescription charges are applicable to patients under 16 years of age

Prescription charge(s) apply to all PGDs which are supplied to patients to take home, unless the patient is exempt.

Cautions (including any relevant action to be taken)	• Caution is advised in ocular hyperaemia as increased systemic absorption may occur *Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. In very red eyes, take advice from a doctor or prescriber* • Burning or stinging on instillation *Inform the patient and advise him/her that this will settle after a minute or two* • Blurring of vision and/or photophobia *Inform patient, parent/carer duration of symptoms* • Completion of skilled tasks *Inform parent/carer and patient they may not be able to undertake skilled tasks for duration of symptoms of blurring/photophobia*

<table>
<tr><td></td><td colspan="2">Initial supply to parent, legal guardian or carer
See algorithm on page 7

Cyclopentolate 0.5% or 1% eye drops</td></tr>
<tr><td>Indicate any off-label use</td><td colspan="2">The use of cyclopentolate 0.5% in children < 3 months is not recommended – see additional information section</td></tr>
<tr><td>Route/method of administration</td><td colspan="2">Topically to the lower conjunctival sac</td></tr>
<tr><td>Dosage and frequency</td><td>Birth to up to 6 months

Parent, legal guardian or carer instils:

One drop cyclopentolate 0.5% applied topically to eye,

If after 10 minutes the pupil remains undilated a further single drop of cyclopentolate 0.5% is to be instilled</td><td>6 months to up to 16th birthday

Parent, legal guardian or carer instils:

One drop cyclopentolate 1% applied topically to eye

If after 10 minutes the pupil remains undilated a further single drop of cyclopentolate 1% is to be instilled</td></tr>
<tr><td>Maximum quantity to be administered and/or supplied</td><td>Supply 2 unit dose packs of cyclopentolate 0.5% to parent, legal guardian or carer</td><td>Supply 2 unit dose packs of cyclopentolate 1% to parent, legal guardian or carer</td></tr>
<tr><td>Maximum or minimum treatment period</td><td colspan="2">2 drops over 10 to 15 minutes</td></tr>
<tr><td>Adverse effects</td><td colspan="2">Cyclopentolate Hydrochloride 0.5%and 1%

Recovery of accommodation occurs within 24 hours

Local Effects

Local irritation and temporary stinging may result following the use of this product. The frequency of this effect occurring is dependent on the concentration instilled

Increased intraocular pressure may occur in predisposed patients

Allergic reactions may rarely occur, manifesting as diffusely red eyes with lacrimation and stringy white mucus discharge</td></tr>
</table>

	Blurred vision and difficulty in focusing Bright light can be uncomfortable for a few hours after receiving the drops <u>Systemic Effects</u> Systemic cyclopentolate toxicity is dose-related and is uncommon following administration of 1% solution and would not be expected to occur following instillation of 0.5% solution. Children are, however, more susceptible to such reactions than adults. Toxicity is usually transient and is manifest mainly by CNS disturbances. Any CNS disturbances are characterised by signs and symptoms of cerebellar dysfunction and visual and tactile hallucinations Peripheral effects typical of anti-cholinergics, such as flushing or dryness of the skin and mucous membranes, have been observed in a small percentage of children at Moorfields Eye Hospital with topical cyclopentolate. Temperature, pulse and blood pressure are not normally affected This list may not represent all reported side effects of this medicine. Refer to the most current SPC for more information available at: www.medicines.org.uk/emc/

Subsequent supply to parent, legal guardian or carer to be used prior to next appointment if patient is not adequately dilated or still accommodating following cyclopentolate 1% eye drops.-
Patient must be 6 months to 16th birthday and have dark irides
See algorithm on page 7

Atropine 1%single unit dose eye drops

Indicate any off-label use (if relevant)	
Route/method of administration	Topically to the lower conjunctival sac.
Dosage and frequency	One drop topically into both eyes for three consecutive days prior to the appointment (but not on the day of the appointment). One unit dose packet for each day.
Maximum quantity to be administered and/or supplied	Supply 3 unit dose packs of atropine 1% in a pre-pack to parent, legal guardian or carer
Maximum or	**One drop only to each eye for three consecutive days**

minimum treatment period	
Adverse effects	• Blurred vision and difficulty in focusing • Swelling and/or redness of eyelids or conjunctivae or watering of the eyes. Gritty, foreign body sensation (possible allergy). • Bright light can be uncomfortable for a few hours after receiving the drops. • Transient dry mouth (rare) • Skin flushing (rare) • Increased body temperature (rare) • Urinary symptoms (rare) • Gastrointestinal symptoms (rare) • Tachycardia (rare) • In extremely rare cases these medicines may cause an acute attack of angle closure glaucoma. Symptoms may include ocular pain, visual blurring, coloured halos around lights and nausea or vomiting. This list may not represent all reported side effects of this medicine. Refer to the most current SPC for more information available at: www.medicines.org.uk/emc/

Records to be kept

The following must all be recorded in the patient's healthcare records	• Full number of PGD (e.g. PGD057Or) • Name and signature (which may be an electronic signature) of the health professional supplying or administering the medicine • Patient identifiers (name/date of birth/hospital number) • Patient allergies and any previous adverse events • How the patient met the criteria of the PGD • Details of the medicine provided, name, strength, dose, frequency, quantity, route and site (if by injection) • Date and time the medicine was supplied or administered • A statement that supply or administration is by

	using a PGD • Patient consent or refusal • Patient exclusion from PGD • Relevant information that was provided to the patient or their carer including Patient Information Leaflet for supplied medicines An annual audit will take place to audit the above records
Macro GP letter	• For all GPs to be informed of all drops being given to instil at home
Adverse drug reaction - Yellow Card	• Any suspected adverse drug reaction, whether to a medicine supplied or administered to the patient by the practitioner or to a medicine already taken by the patient must be reported to a doctor immediately or as appropriate. • If a Yellow Card is filled out – keep a copy in the patient's healthcare record

Patient information

Written and verbal information to be given to patient or carer	Protection of the eye from rubbing the eye(s), it is common for children to rub the eye following instillation of eye drops. Care to be taken with school activities e.g. sports on the day of the appointment. See leaflets in appendix A and B Store below 25°C. Protect from light. Keep out of the reach of children. Only instil drops in the eye
Follow up advice to be given to patient or carer	• Advise patient to attend any A&E if they become unwell and have left the premises • Advise patient to contact A&E or GP if any side effects become serious or unbearable • Advice on recognising side effects and what to do (see side effects) • Advice on where to seek help if treatment fails or condition worsens • Letter to GP following clinic visit.

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Additional information

Custom and practice at Moorfields Eye Hospital has been the provision of dilating eye drops via Patient Group Direction from birth.

At Moorfields Eye Hospital, we have noted facial flushing in patients using cyclopentolate drops.

Cyclopentolate eye drops are not recommended in children < 3 months.
The licensed dose from 3 months - 12 years is 1 drop of a 1% solution to each eye.

We use cyclopentolate 0.5% in children from birth to 6 months of age to ensure that they have full cycloplegia. They have been given into the designated eye prior to fundoscopy and refraction at the following dose:

One drop cyclopentolate 0.5% applied topically to eye,

If after 10 minutes the pupil remains undilated a further single drop of cyclopentolate 0.5% is to be instilled

We use cyclopentolate 1% in children from 6 months up to 16th birthday to ensure that they have full cycloplegia. They have been given into the designated eye prior to fundoscopy and refraction at the following dose:

One drop cyclopentolate 1% applied topically to eye

If after 10 minutes the pupil remains undilated a further single drop of cyclopentolate 1% is to be instilled

This has been considered to be safe and clinically effective custom and practice in many eye units including Moorfields Eye Hospital.

I therefore authorise the use of cyclopentolate 1% eye drops to be administered in Patient Group Directions [PGD's] as stated for the use as above.

Signed: Dated:

Health Professionals' Agreement to Practice Statement

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

Name of health professional	Signature	Senior healthcare professional/line manager authorising optometrist	Date

Appendix A: Patient Information Leaflet (cyclopentolate)

Orthoptic clinic contact number: ……..

USING DROPS AT HOME FOR EYE TESTS

You have been given 0.5 % / 1% **Cyclopentolate eye drops** (delete as appropriate) to be used in your child's eyes on the day of your next visit. These drops are used to widen the pupil (black central area of the eye) and relax the muscles inside the eye that control the focusing. This will enable us to examine the inside of the eyes and measure whether there is a need for glasses.

HOW TO USE THE EYE DROPS

1. Ensure hands are clean.

2. Either with your child lying down or in a seated position looking up, gently pull the eyelids apart and squeeze one drop into the lower lid. (If you're unsure if the drop has gone in, then instil another).

3. Repeat with the other eye.

4. Wash your own hands to avoid getting any in your own eyes.

Depending on how dark your child's eyes are you may be asked to instil a second drop into both eyes.

Please instil first set of drops …… hour before appointment time.

Please instil second set of drops…… hour / hours before appointment time.

FURTHER INFORMATION

The drops you have used in your child's eyes will make their vision blurry for several hours, so if your child reports this, it is normal. If returning to nursery / school after the appointment please inform them your child has had eye drops. It is also likely to make them slightly more sensitive to light, so particularly if it is a sunny day please prepare with sunglasses or a sun hat to make them more comfortable. The pupils may remain dilated for up to a week, however they usually return to normal within 24 hours.

SIDE EFFECTS

Very occasionally children can react to the drops causing a raised temperature. For this reason if your child has a temperature on the day of their appointment please do not use the drops and telephone the department on **Tel……**

Reactions to the drops are rare however if your child develops a temperature after using them please contact your GP for advice.

Updated June 2018

Appendix B: Patient Information Leaflet (atropine sulphate 1%)

Orthoptic clinic contact number: ……..

USING ATROPINE FOR EYE TESTS

You have been given Atropine drops to use in your child's eyes before your next visit.

These drops will widen the pupil (the black centre of the eye) and relax the muscles inside the eye. This will enable us to examine inside the eye and measure whether there is any need for glasses.

How to use the Atropine drops

First, wash your hands. Then, with your child lying down, gently pull the eyelids apart and squeeze one drop into the lower lid sac. Repeat with the other eye.

You will need to use the drops in this way for 3 consecutive days prior to your appointment (**but not on the day of the appointment**).

Date (first day of drops)……

Date (second day of drops)……..

Date (third day of drops)……

Date of appointment (no drops)……

You will notice that the pupils of the eyes gradually get larger and your child may tell you that their vision is blurred. This is due to the relaxation of the muscles inside the eye and is completely normal with these drops.

If you have been given ointment instead of drops, you use it in the same way, putting a small amount of ointment inside the lower lid each time.

After you have used the drops/ointment make sure you wash your hands to avoid getting any Atropine into your own eyes by mistake. If your child rubs their eyes after instillation, you will need to wash their hands also to avoid them swallowing any of the Atropine.

When using Atropine, you should notify your childs school / nursery. If you attend any other medical appointments let the doctor or healthcare professional know that Atropine is being used.

NOTE

Occasionally children can react to Atropine, showing raised temperature, hot , dry skin and sickness. This is rare but if if it occurs, stop using the Atropine and contact your GP, NHS Helpline or go to your local A&E department.

As with all medicines, keep out of reach of children at all times.

If you have any questions about using Atropine, please contact Moorfields Eye Clinic on **TEL……..**and we will be pleased to help.

Appendix C: Labels for supplied medication

Cyclopentolate 0.5% eye drops 2 unit dose containers:

Cyclopentolate 0.5% Minim (Preservative Free)
(2 x Single Use Containers)
Eye drops to be instilled on this date: …….
Instil one drop into both eyes……. hours before appointment time.
If required, instil a second drop into both eyes …….. hours before appointment time.
Discard each minim after single use.
Patient name…….. Date of issue…..……..
Batch no: xxxxxxx Expires: xx xxx xxxx
Dispensed by: Checked by:
Store in a dry place below 25°C. Protect from light.
Keep out of sight and reach of children.

Cyclopentolate 1%eye drops 2 unit dose containers:

Cyclopentolate 1% Minim (Preservative Free)
(2 x Single Use Containers)
Eye drops to be instilled on this date: …….
Instil one drop into both eyes……. hours before appointment time.
If required, instil a second drop into both eyes …….. hours before appointment time.
Discard each minim after single use.
Patient name…….. Date of issue…..……..
Batch no: xxxxxxx Expires: xx xxx xxxx
Dispensed by: Checked by:
Store in a dry place below 25°C. Protect from light.
Keep out of sight and reach of children.

Atropine 1% eye drops 3 unit dose containers:

Atropine 1% Minims (Preservative Free)
(3 x Single Use Containers)
Instil one drop into both eyes for 3 consecutive days,
on these dates:

…….
…….
……..

Discard each minim after single use.
Patient name…….. Date of issue…..……..
Batch no: xxxxxxx Expires: xx xxx xxxx
Dispensed by: Checked by:
Store in a dry place below 25°C. Protect from light.
Keep out of sight and reach of children.

Appendix D: PGD Development Checklist

Evaluation Form For: Patient Group Direction (PGD) for the supply of cyclopentolate 0.5%, or cyclopentolate 1% or atropine 1% eye drops by registered orthoptists to parents, legal guardians or carers of paediatric patients who require: either refraction or fundoscopy with refraction in Moorfields Eye Hospital NHS Foundation Trust			
Completed by: Kelly Mackenzie	**Date:** 27 Feb 2019		
	YES	**NO**	**COMMENT**
The PGD title accurately reflects the aims of the PGD	✓	☐	If no, review & amend
Lead author is a health professional authorised to develop and practice under a PGD	✓	☐	If no, cannot proceed
Lead author has specific experience and competencies as outlined in the Trust PGD Policy	✓	☐	National guidance
Co-authors include a senior clinical pharmacist and a doctor (permanent SpR or above)	✓	☐	Legal requirement
The health professional who practice under the PGD are legally authorised to do so	✓	☐	Legal requirement
Latest approved Moorfields PGD template used	✓	☐	Trust requirement
Moorfields Logo in header	✓	☐	Legal requirement
Layout is logical and easy to follow	✓	☐	Particularly if more than one medicine is included in PGD
If new PGD, has a PGD proposal form been completed and sent to NMSMG	✓	☐	Trust requirement
If new PGD, has proposal been discussed and agreed	✓	☐	If no, discuss and agree with service lead

with service lead			
If new PGD, audit plan has been identified and discussed with Professional Lead	✓	☐	If no, this must be actioned
If PGD for review, must be submitted for re-approval three months before expiry	✓	☐	Trust requirement
If for review, audit evidence/report has been submitted to DTMMC	✓	☐	Trust requirement
Single medicine PGD	☐	✓	If no, go to next question
Multi-medicine PGD	✓	☐	If yes, each monograph must meet all requirements
Relevant tasks and responsibilities have been undertaken by all involved in development of PGD	✓	☐	If no, specify details and reasons here
Any related guidelines are attached (as appendices)	✓	☐	Trust requirement
Any related patient information is attached (as appendices)	✓	☐	All patient information must be approved by service lead
Staff qualifications / training / competency requirements provided with related training information	✓	☐	Trust requirement
Evaluation of Clinical Content section (To be completed by the lead author) PGD must contain the following:			
	YES	**NO**	**COMMENT**
Clinical condition or situation to which the PGD applies	√	☐	Legal requirement

The clinical condition or situation (Inclusion criteria)	✓	☐	Legal requirement
Clinical criteria for exclusions (Exclusion criteria)	✓	☐	Legal requirement
Action if excluded from PGD	✓	☐	Legal requirement
Action if patient declines treatment	✓	☐	Legal requirement
Arrangements for referral for medical advice	✓	☐	
Name, form and strength of medicine	✓	☐	Legal requirement
Legal category	✓	☐	Legal requirement
Cautions	✓	☐	Legal requirement
Action to be taken under Cautions	✓	☐	Legal requirement
Indicate any off-label use	✓	☐	Legal requirement
Route/dose/frequency	✓	☐	Legal requirement
Maximum quantity for administration or supply	✓	☐	Legal requirement
Maximum or minimum treatment period	✓	☐	Legal requirement
Action for adverse events	✓	☐	Legal requirement
Written and verbal information to be given to patient or carer	✓	☐	Legal requirement

Details of any follow up action including: Information to be given to patient and how information given is to be documented	✓	☐	Legal requirement
Any appended guidelines or references have been attached	✓	☐	
Details of what records are to be kept	✓	☐	Legal requirement
All references are up to date and are in standard format	✓	☐	
Additional checks (to be completed by link pharmacist) **Completed by Jill Bloom 21 Feb 2019**			
	YES	**NO**	**COMMENT**
Name of medicine (generic if appropriate)	✓	☐	Legal requirement
Strength	✓	☐	Legal requirement
Legal category of medicine / preparation	✓	☐	Legal requirement
Name / strength / form written in BNF nomenclature	✓	☐	Trust requirement
Dosage details are in the current BNF(C) / SPC	✓	☐	If no, provide explanation and references
Warning / interactions / side effects are in the current BNF(C) / SPC	✓	☐	If no, provide explanation and references
Dose / dosage details	✓	☐	Legal requirement
Is it a black triangle medicine?	☐	✓	If yes, states reasons for use & provides evidence Legal requirement

Is it an unlicensed medicine?	☐	✓	If yes, do not proceed. PGD cannot be used.
Is the medicine being used outside of SPC ("off label" use)	✓	☐	If yes, must be supported by evidence AND best clinical practice. Have the relevant Trust procedures been followed to obtain approval for inclusion? If yes, state reasons for use and include evidence Legal requirement
Route of administration	✓	☐	Legal requirement
Frequency	✓	☐	Legal requirement
Maximum or minimum treatment period	✓	☐	Legal requirement
Quantity	✓	☐	Legal requirement
Pack size specified if available and appropriately labeled if TTO	☐	☐	Legal requirement
Side effect / warnings / adverse effects	✓	☐	Legal requirement
Any resource links provided are up to date	✓	☐	If no, review and update links
Is/Are prescription charge(s) required and specified	☐	✓	Prescription charge(s) apply to all PGDs which are supplied to patients to take home, unless the patient is exempt. Prescription charge(s) are not payable for medicines which are administered under a PGD
Pre DTMMC submission checks			

	YES	NO	COMMENT
Content agreed by Non-Medical Supply of Medicines Group Date: 24 Jan 19	✓	☐	
Local Service Meeting approval for the PGD granted Date: 22 Jan 2019	✓	☐	
Checklist completed by the Lead Author	✓	☐	
Copy of completed checklist sent to DTMMC with draft PGD Date: 18 April 2019	✓	☐	