University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of Fluorescein 2% eye drops or 1mg ophthalmic strips

By Registered Practitioners working at University Hospital of Derby and Burton

Documentation details

Reference no:	UHDB 161
Version no:	1
Valid from:	30/06/2022
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Expiry date:	29/06/2025

Change history

Version number	Change details	Date

Glossary

Abbreviation	Definition

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD (or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
VICKI MEREDITH	SENIOR SISTER Eye Clinic
MR ANIL KUMAR	CONSULTANT OPHTHALMOLGIST
LISA NOCK	PHARMACIST

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
n/a	n/a	n/a

2. Organisational authorisations

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

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
All UHDB sites and in clinics operated by UHDB staff at peripheral sites
Limitations to authorisation
No limitations – however, note that strips do not have a pharmaceutical license and therefore are not formally covered by PGD legislation which is for medications only. Strips are medical devices and may be used as an alternative to eye drops (as a locally agreed protocol) and have therefore been included in this PGD to provide clarity on the pathway options and to promote best practice.

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	**James Hooley**	**Signed copy held by Pharmacy**	**30/06/2022**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Pharmacist *Clinical Pharmacist from PGD working group*	**LISA NOCK**	**Signed copy held by Pharmacy**	**09/05/2022**
Lead for Ophthalmology *Doctor*	**MR JAMES TILDESLEY**	**Signed copy held by Pharmacy**	**29/06/2022**
Senior Sister Outpatients *Registered Professional representing users of the PGD*	**VICKI MEREDITH**	**Signed copy held by Pharmacy**	**19/05/2022**

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

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	Qualified NMC Registered Nurse HCPC Registered Orthoptist Health Care Professionals (who can legally operate under PGD's) who have undergone additional training to administer drops outlined in this PGD and have been assessed as competent.
Initial training	Completion of all Essential-to-role training as outlined in the UHDB PGD policy. Individual has read and understood full content of this PGD and signed authorisation (section 7) The registered Healthcare Professional will undertake training and will ensure he/she is competent in all aspects of this treatment.
Competency assessment	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 either authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.
Ongoing training and competency	Health care professionals must complete annual basic life support and anaphylaxis training to administer drugs under this PGD.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• Diagnosis and location of damage to the cornea including abrasions, ulcers and foreign bodies. • Detection of leaking wound following phacoemulsification • Corneal staining prior to eye examination including Goldmann tonometry.
Criteria for inclusion	• Patients attending eye casualty where visualisation of the cornea is required • Diagnostic examinations including Goldmann tonometry. • Consent gained – if under 16 years consider requirements for consent. • Can be administered to Adults and Children.
Criteria for exclusion	• Consent not gained • Not be used with soft contact lenses. • Known or suspect hypersensitivity reaction to any of the ingredients.
Cautions including any relevant action to be taken	Pregnancy and Breast-feeding patients. Seek advice from Consultant/Doctor or Pharmacist.
Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes • Record advice given to patient on alternative treatment • Refer to medical staff if appropriate
Action to be taken if the patient or carer declines treatment	• Document reason for refusal given • Advise patient on alternative treatment / refer to medical staff if appropriate
Arrangements for referral for medical advice	*The practitioner is expected to use their own clinical judgement and refer patients to the relevant service e.g. OOH GP's, A&E, MIU's or walk in centres as they see fit.*

5. Description of treatment

Name, strength & formulation of drug	Fluorescein 2% eye drops single dose units (minims) Fluorescein 1mg ophthalmic strips
Legal category	Prescription-only medicine (POM). Note: Ophthalmic strips are classified as a medical device and are administered under local protocol but mentioned here for clarity
Route / method of administration	Instilled into the eye (s) to be examined.
Indicate any off-label use (if relevant)	Not Applicable
Dose and frequency of administration	Drops: Sufficient drops to stain the cornea. Wash away excess with Sodium chloride 0.9% (minims) Ophthalmic strips: ONE strip to be used per eye. Moisten strip with

	sterile water prior to application
Duration of treatment	Once only per eye for examination purposes
Quantity to be supplied (leave blank if PGD is administration ONLY)	n/a
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: Store below 25 (degrees). Do not freeze. Protect from light.
Drug interactions	*The following interactions have been identified and should be considered where it is known a patient is on the following medicines:* None Known
Identification & management of adverse reactions	The following side effects are common: • Transient stinging or blurring of vision may occur • Symptoms of allergic-type reactions and anaphylaxis have been reported following topical ophthalmic administration of fluorescein sodium and may manifest as: • Allergic conjunctivitis or peri-orbital oedema. • Immune system disorders: anaphylactic reactions • Skin and subcutaneous tissue disorders: urticaria, rash.
Management of and reporting procedure for adverse reactions	• 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. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use. • ***Anaphylaxis/Emergency Treatment at Derby and main Queens site:*** • Call the crash team via switchboard • ***Anaphylaxis/Emergency treatment (at all other sites):*** ➢ Call 999 ➢ Summon help ➢ Maintain airway ➢ CPR • Follow trust resuscitation guidelines •
Written information to be given to patient or carer	Not routinely required for administration in the department. May be given a copy of the marketing authorisation holder's patient information leaflet (PIL) provided with the product if required.
Patient advice / follow up treatment	Advise patient to remove contact lenses before drop instillation and do not reinsert until the effects of the drops have completely worn off (i.e. once vision returns to normal and yellow discolouration subsides).

	Do not rub the eye and keep free of particles for one hour. Surrounding tissue may be stained, and nasal discharge will be green/yellow for a short time. Verbal advice on why drug is administered and the action of the drug. Monitor for sensitivity reactions and subsequent management of any adverse events.
Records	Document using the system in place for your clinical area which may include: EPMA, patients notes, treatment card, Eye casualty card, Ophthalmic care pathway. Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following: • 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 e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether supplied and/or administered via Patient Group Direction (PGD) [strips are administered by protocol] Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

6. Key references

Key references	• *Electronic Medicines Compendium* Minims Fluorescein Sodium 2%, Eye drops solution - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) • *Electronic BNF https://bnf.nice.org.uk/* • *NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2*

7. Registered health professional authorisation sheet

PGD Name [version]: Fluorescein 2% eye drops and 1mg ophthalmic strips [v1]
PGD ref: UHDB161

Valid from: 30/06/2022 **Expiry date: 29/06/2025**

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional
By signing this patient group direction you are indicating that

a) You agree to and understand all content and commit to only work within this framework.
b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

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**

Authorising manager / Assessor

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.