University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of MAXITROL EYE DROPS By Ophthalmic Nurse Practitioners at UHDB sites

Documentation details

Reference no:	UHDB201
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Change history

Version number	Change details	Date
2.0	New UHDB format	06/10/2022

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
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
For use by nursing staff who have completed additional training to include assessment and diagnosis only

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer	James Hooley	**Signed copy held by Pharmacy**	19/10/2022

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Pharmacist	**LISA NOCK**	**Signed copy held by Pharmacy**	**06/10/2022**
Doctor	**MR JAMES TILDESLEY**	**Signed copy held by Pharmacy**	**06/10/2022**
Senior Sister Outpatients	**VICKI MEREDITH**	**Signed copy held by Pharmacy**	**06/10/2022**

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 - Health Care Professionals who have undergone additional training to administer drug outlined in this PGD and been assessed as competent.
Initial training	- Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Completion of local competency assessment for Ophthalmic Nurse Practitioners - Individual has read and understood full content of this PGD and signed authorisation (section 7) - Completion of on line PGD training - 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	- The nurse will have due regard for the NMC Code of professional practice for nurses and midwives 2015, and the RCN/RPS guidelines relating to plus other relevant Department of Health Guidelines - 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	To treat marginal keratitis
Criteria for inclusion	• Patients aged 16 years and over diagnosed with clinical condition to which this PGD applies. Condition should be diagnosed by an appropriately trained ophthalmic nurse following the Diagnosis and Treatment guidelines for nurse practitioners.
Criteria for exclusion	• Consent not gained • Previous local or systemic reactions to the medicine • Known or suspected hypersensitivity to any of the ingredients / excipients • Herpes Simplex Keratitis • Vaccinia, varicella, and other viral infection of cornea or conjunctiva. • Fungal disease of ocular structures. • Mycobacterial ocular infections. • Pregnancy and breast feeding.
Cautions including any relevant action to be taken	Seek further medical advice for the following: • Patients who have had prolonged use of ophthalmic corticosteroids as this may result in ocular hypertension and/or glaucoma, and posterior subcapsular cataract formation. Intraocular pressure should be checked routinely and frequently. The risk of corticosteroid-induced raised intraocular pressure and/or cataract formation is increased in predisposed patients (e.g. diabetes).
Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes • Inform doctor • Advise patient on alternative treatment •
Action to be taken if the patient or carer declines treatment	• Document advice given • Inform doctor • Advise patient on alternative treatment
Arrangements for referral for medical advice	Inform doctor or suitably qualified specialist in ophthalmology. Discuss potential consequences/referral/records to be kept.

5. Description of treatment

Name, strength & formulation of drug	Maxitrol Eye drops suspension
Legal category	Prescription Only Medicine (POM)
Route / method of	1 drop Instilled into the eye(s) to be treated

administration	
Indicate any off-label use (if relevant)	None
Dose and frequency of administration	Apply one drop to each affected eye up to six times daily.
Duration of treatment	1week
Quantity to be supplied (leave blank if PGD is administration ONLY)	*1 Bottle of suitably overlabelled stock supplied by pharmacy* Labelling must meet the requirements outlined in Trust PGD Policy and associated training. The Pharmacy department over-label packs to meet legal requirements for supply. If you do not hold these appropriately over-labelled packs in stock, then a supply to patients is not appropriate. A prescription charge should be levied in clinical areas who are required to issue NHS prescription charges. Over the counter supplies of paracetamol are cheaper for the patient; signpost where possible
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: • Store below 25°C. 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:* • No interaction studies have been performed on this preparation. A detailed list of potential drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions	• Transient blurring of vision • Keratitis, photophobia, mydriasis, eyelid ptosis, eye swelling, eye pruritis. Ocular discomfort, foreign body sensation in eyes, eye irritation, ocular hyperaemia, increased lacrimation. • Intraocular pressure increase • headache • In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids. • Cushing's syndrome and /or adrenal suppression associated with systemic absorption of ocular dexamethasone may occur after intensive or long-term continuous therapy in predisposed patients. In these cases, treatment should be progressively discontinued. • Corticosteroids may reduce resistance to and aid in the establishment of nonsusceptible bacterial, fungal, parasitic or viral infections and mask the clinical signs of infection or may suppress hypersensitivity reactions to MAXITROL eye drops, suspension. • Topical ophthalmic corticosteroids may slow corneal wound

	healing. A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
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:** Follow your local medical emergency procedures (e.g. 2222 / 3333 / 9999 procedures) ➢ Summon help ➢ Maintain airway ➢ CPR ➢ Follow trust resuscitation guidelines
Written information to be given to patient or carer	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.
Patient advice / follow up treatment	• Advise that stinging may occur on instillation. • If transient blurred vision occurs upon instillation, the patient must wait until the vision clears before driving or using machinery. • Do not wear contact lenses for duration of treatment. • Nasolacrimal occlusion after administration is recommended. This may reduce the systemic absorption of medicinal products administered via the ocular route and result in a decrease in systemic adverse reaction. • Shake the bottle before use. • If more than 1 opthalmic preparation is being used, these should be administered at least 5 minutes apart. Eye ointment should be administered last. • The individual/carer should be advised to seek medical advice in the event of an adverse reaction. • Patients should be advised to consult a doctor if ocular pain, redness, swelling or irritation worsens or persists
Records	• Medical record/notes 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 • 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) 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* Maxitrol Eye Drops - 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]: Ophthalmic Nurse Practitioners – Maxitrol [v1]
PGD Ref: UHDB201
Valid from: 19/10/2022 Expiry date 18/10/2025

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.