University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of Carbomer Eye Gel 0.2%
By Registered Practitioners working at University Hospitals of Derby and Burton

Documentation details

Reference no:	UHDB160
Version no:	1
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Expiry date:	

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 OPHTHALMOLOGIST
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

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer	**James Hooley**	**Signed copy held by Pharmacy**	14/06/2022

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Pharmacist	**LISA NOCK**	**Signed copy held by Pharmacy**	**09/05/2022**
Lead for Ophthalmology	**JAMES TILDESLEY**	**Signed copy held by Pharmacy**	**09/06/2022**
Senior Sister Outpatients	**SSR. VICKI MEREDITH**	**Signed copy held by Pharmacy**	**29/04/2022**

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 Nurses - HCPC registered Orthoptist - Health care Professional (who can legally operate under PGD and has 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 professional must complete annual basic life support 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	Dry eye condition including keratoconjunctivitis sicca, unstable tear film (using 0.2% preparation) Post intravitreal injection patients
Criteria for inclusion	Adult and paediatric patients with above conditions
Criteria for exclusion	• Consent not gained • previous local or systemic reactions to the medicine • Known hypersensitivity to the product or lanolin alcohols or the below components Benzalkonium chloride 0.01% Sorbitol Sodium hydroxide
Cautions including any relevant action to be taken	• Do not use with contact lenses
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 The practitioner is expected to use their own clinical judgment and refer patients to OOHs GP/A&E/minor injury unit/Walk in centre as they see fit. Provide appropriate details e.g Eye casualty opening times

5. Description of treatment

Name, strength & formulation of drug	0.2% w/w Carbomer 980 Ph.Eur
Legal category	P / GSL / medical device (depending on brand obtained)
Route / method of administration	instilled into the conjunctival fold of the eye
Indicate any off-label use	None

(if relevant)	
Dose and frequency of administration	• Adults (including the elderly) and children: • One drop to be instilled into the conjunctival fold of each affected eye 3 - 4 times daily or as required, depending on the degree of discomfort.
Duration of treatment	7 days
Quantity to be supplied (leave blank if PGD is administration ONLY)	One tube for each eye of pharmacy issued overlabelled stock, with the patients name and date of supply added.
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: The product should be transported in the original packaging. It should be stored below 25°C. Any remaining gel should be discarded 28 days after first opening the tube, or if the product reaches the expiry date printed on the tube.
Drug interactions	None known A detailed list of 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	The following side effects are common: • Transient blurring of vision, if affected, the patient should be advised not to drive or operate hazardous machinery until normal vision is restored. • Transient stinging • Do not use with contact lenses 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 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	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product. Label and explain the drug with appropriately
Patient advice / follow up treatment	The individual /carer should be advised to seek medical help in the event of adverse reaction Verbal information should be given on the reason for drug administration ,action of the drug, side effects and subsequent management
Records	Document using the system in place for your clinical area which may include: ePMA; patient 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) 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 http://www.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]: UHDB – All Areas - CARBOMER 0.2% EYE GEL [v1]
PGD ref: UHDB160

Valid from: 14/06/2022 Expiry date: 13/06/2025

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.