University Hospitals of Derby and Burton
NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of CHLORPHENAMINE INJECTION

By Registered Nurses, Emergency Nurse Practitioners (ENP), Emergency Care Practitioners (ECP) and Emergency Physiotherapy Practitioners (EPP) In Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals

Documentation details

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Change history

Version number	Change details	Date
1	New UHDB format	25/04/2023

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
Dr Venkat Thungala	Doctor
James Kerr	Pharmacist
Alannah Davies	Representative of RNMHP Group

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
In Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals
Limitations to authorisation
Nil

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Office *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	James Hooley	**Signed copy held in Pharmacy**	**26/05/2023**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Divisional Pharmacist *Clinical Pharmacist from PGD working group*	**James Kerr**	**Signed copy held in Pharmacy**	**04/05/2023**
Consultant *Doctor*	**Dr. Venkat Thungala**	**Signed copy held in Pharmacy**	**23/05/2023**
Interim Matron Acute Medicine QHB *Registered Professional representing users of the PGD*	**Danielle Murphy**	**Signed copy held in Pharmacy**	**26/04/2023**

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	Registered professional with current professional registration operating within their usual scope of practice. Must be a profession permitted by current legislation to practice under a patient group direction.
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) - Completion of Medicines Management Drug Assessment - Deemed competent by their line manager to undertake the clinical assessment of a patient leading to a diagnosis that requires treatment according to the indications listed in this PGD and Trust clinical guidelines.
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 senior individual responsible for authorising individuals to act under the PGD and further training provided as required.
Ongoing training and competency	- Annual Medicines Safety Training (essential to role) - Review/repeat initial training above when this PGD is revised - The registered healthcare practitioner will ensure Anaphylaxis/CPR training is kept updated yearly. - The registered healthcare professional must actively take part in CPD and annual individual performance reviews. - Regular training and updating in safeguarding children and vulnerable adults as per trust policy
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	• Control of severe allergic reactions when oral chlorphenamine is inappropriate • For acute allergy (once patient has been stabilised with use of adrenaline - follow National/Trust guidelines on anaphylaxis).
Criteria for inclusion	Adults and children over 1 years old presenting with symptoms of: • Angio-neurotic edema • Severe allergic reaction resulting in rash or inflammation and itchiness • Acute anaphylaxis (to be used in accordance with national/trust guidelines secondary to adrenaline)
Criteria for exclusion	• Children under 1 years old • Previous allergy to chlorphenamine or any other ingredient in product • Treated with monoamine oxidase inhibitors (MAOI's) within the last 14 days • Avoid use in pregnancy or those breast feeding where possible
Cautions including any relevant action to be taken	• Monitor for excessive drowsiness and advised patient/carer accordingly. • Patient should seek medical advice if any side effects persist. • Chlorphenamine, in common with other drugs having anticholinergic effects, should be used with caution in epilepsy; raised intra-ocular pressure including glaucoma, prostatic hypertrophy, severe hypertension or cardiovascular disease, bronchitis, bronchiectasis and asthma, hepatic disease and thyrotoxicosis. Children and the elderly are more likely to experience the neurological anticholinergic effects. Consider alternative treatment in this scenario.
Action to be taken if the patient is excluded	• **Refer to a Doctor (e.g. GP or A&E) for further assessment**
Action to be taken if the patient or carer declines treatment	• Discuss need for treatment • Document advice given • Advise patient on alternative treatment
Arrangements for referral for medical advice	• Follow up A&E if in minor injuries setting when used in conjunction with adrenaline. • Follow up GP for potential allergy testing if resulting in severe reaction with unknown cause.

5. Description of treatment

Name, strength & formulation of drug	Chlorphenamine Maleate Intramuscular Injection 10mg/1ml
Legal category	POM
Route / method of	Intramuscular Injection (IM)

<table>
<tr><td>administration</td><td></td></tr>
<tr><td>Indicate any off-label use (if relevant)</td><td>None</td></tr>
<tr><td>Dose and frequency of administration</td><td><table><tr><th>AGE</th><th>DOSE</th></tr><tr><td>1 to 5 years</td><td>2.5mg (Max 4 doses a day)</td></tr><tr><td>6 to 12 years</td><td>5mg (Max 4 doses a day)</td></tr><tr><td>12 to 18 years</td><td>10mg (Max 4 doses a day)</td></tr><tr><td>Adults 18+</td><td>10mg (Max 4 doses a day)</td></tr></table></td></tr>
<tr><td>Duration of treatment</td><td>Doses may be repeated as above if necessary and according to response.</td></tr>
<tr><td>Quantity to be supplied (leave blank if PGD is administration ONLY)</td><td>n/a</td></tr>
<tr><td>Storage</td><td>Store below 25°C and protect from light.
Do not refrigerate or freeze.
The storage at temperatures higher than 25°C could lead to precipitation inside the solution. Do not use the product if solid particles are observed inside the solution.

Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below:

Available from the electronic Medicines Compendium website, available at: <https://www.medicines.org.uk/emc/product/10595> Accessed on 14/12/21.</td></tr>
<tr><td>Drug interactions</td><td>• Concurrent use of chlorphenamine and hypnotics or anxiolytics may potentiate drowsiness. Concurrent use of alcohol may have a similar effect.
• Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity.
• The anticholinergic effects of chlorphenamine are intensified by MAOIs</td></tr>
<tr><td>Adverse reactions</td><td>• Common:
Concentration impaired, coordination abnormal, dizziness, Fatigue, Nausea, Vision blurred, paradoxical excitation in children and confusional psychosis in the elderly can occur.
Rare:
• Urinary retention, dry mouth, tremor, palpitations, blood dyscrasias, headaches, exfoliate dermatitis and tinnitus.</td></tr>
<tr><td>Management of and reporting procedure for adverse reactions</td><td>• 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</td></tr>
</table>

	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. • If Anaphylaxis occurs treat as per local emergency protocols and transfer to A&E via 999 if appropriate to area.
Written information to be given to patient or carer	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product or printed from medicines.org.
Patient advice / follow up treatment	• Reassure patient • Dial (9) 999 for urgent transfer to acute hospital setting for further treatment and observation if required in use of anaphylaxis treatment, monitor BP, ECG, CPR, Pulse oximetry. If required, commence CPR, document administration of chlorphenamine and adrenaline in transfer notes and MAR. • Follow up GP for review if not used in anaphylaxis treatment. • Explain treatment and course of action • Advise patient to not operate heavy machinery for minimum 24 hours, do not drink alcohol. • Advise carers, children may be drowsy • Avoid allergen contact as much as possible • Seek medical advice if side effects continue or persist • Elderly patients to be advised of increased risk of falls (especially if increased confusion/sedation)
Records	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 and that this was done 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	• Expired "PGD for administration of CHLORPHENAMINE INJECTION by NMHP employed by QHB in MIU" expired • 31/10/2021 at community hospitals • Electronic Medicines Compendium: Available at: https://www.medicines.org.uk/emc/product/3351/smpc Accessed 14/12/21 • Electronic BNF, Available at: https://bnf.nice.org.uk/drug/chlorphenamine-maleate.html. Accessed 8/1/22. • Resus Guidelines: Emergency treatment of Anaphylaxis 2021. Available at :https://www.resus.org.uk/sites/default/files/2021-05/Emergency%20Treatment%20of%20Anaphylaxis%20May%202021_0.pdf> Accessed 8/1/22. • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • https://medusa.wales.nhs.uk

7. Registered health professional authorisation sheet

PGD Name [version]: Emergency Department, Ambulatory Care QHB and MIU SJCH and SRP – Chlorphenamine Injection [v1]
PGD ref: UHDB243

Valid from: 26/05/2023 Expiry date: 25/05/2026

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.