University Hospitals of Derby and Burton
NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply and/or Administration of CHLORPHENAMINE MALEATE 2mg/5ml syrup and 4mg tablets 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

Reference no:	UHDB119
Version no:	V2.0
Valid from:	28/11/2024
Review date:	28/05/2027
Expiry date:	27/11/2027

Change history

Version number	Change details	Date
1	Use of new UHDB template	May 2021
2	Scheduled review and update. No clinical change.	October 2024

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 Venkata Thungala	Consultant Emergency Medicine
Nida Halim	Pharmacist
Nadine Watson	Emergency Nurse Practitioner

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
N/A

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medication Safety Officer *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	James Hooley	**Signed copy held by Pharmacy**	**28/11/2024**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Pharmacist *Clinical Pharmacist from PGD working group*	**Nida Halim**	**Signed copy held by Pharmacy**	**01/11/2024**
Lead ED Consultant *Doctor*	**Dr Venkata Thungala**	**Signed copy held by Pharmacy**	**14/11/2024**
Senior ENP *Registered Professional representing users of the PGD*	**Nadine Watson**	**Signed copy held by Pharmacy**	**29/10/2024**

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 including core PGD training. • Individual has read and understood full content of this PGD and signed authorisation (section 7) • Completion of Medicines Management Drug Assessment
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.
On-going training and competency	• Annual Medicines Safety Training (essential to role) • Organisation PGD eLearning • Review/repeat initial training above when this PGD is revised • Up to date mandatory training including anaphylaxis/CPR. • 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	• Symptomatic relief of allergy such as hay fever, urticaria, food allergy, drug reactions • Relief of itch associated with chickenpox
Criteria for inclusion	Adults and children over 1 year presenting with Allergy symptoms of: • Food Allergy • Allergic Rash • Drug and serum reactions • Insect bites • Hayfever • Itch associated will illness e.g. chicken pox • Consent gained – if under 16 years consider requirements of consent.
Criteria for exclusion	• Consent not gained • Children under 1 year • Pregnancy or breast feeding • Patients treated with monoamine oxidase inhibitors (MAOI) in the last 14 days • Known allergy to chlorphenamine or any other ingredients in the product see references • Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.
Cautions including any relevant action to be taken	• Elderly patients and children are more susceptible to adverse reactions such as confusional psychosis and other neurological anticholinergic effects • Known renal or hepatic impairment - refer to GP/Prescriber • Epilepsy, prostatic hypertrophy, pyloroduodenal obstruction, raised intra-ocular pressure including glaucoma, severe hypertension or cardiovascular disease; bronchitis, bronchiectasis and asthma, urinary retention – refer GP/Prescriber • Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity • Note tablets contain Lactose • Note syrup contains sucrose and should be taken into account when treating patients who have diabetes mellitus • Note syrup contains ethanol which can be harmful to those suffering with or being treated for alcoholism.
Action to be taken if the patient is excluded	If red flags/anaphylaxis treat accordingly following guidelines • Record reasons for exclusion in patient notes • Advise patient on alternative treatment • Refer to a prescriber if appropriate
Action to be taken if the patient or carer declines treatment	• Explain to the patient the importance of treatment. • Offer alternative intervention/treatment. • Document in medical notes the reason for refusal, action taken, advice given • Refer to a prescriber if appropriate

Arrangements for referral for medical advice	Refer to the appropriate medical practitioner in the care pathway

5. Description of treatment

Name, strength & formulation of drug	Chlorphenamine Maleate 2mg/5mls syrup and 4mg tablets
Legal category	Pharmacy-only Medicine (P)
Route / method of administration	Oral
Indicate any off-label use (if relevant)	Not applicable
Dose and frequency of administration	

Age	Dose	Frequency	Max amount in 24 hours
Syrup			
12-23 months	2.5ml (1mg)	Every 12 hours	5ml (2mg)
2-5 years	2.5ml (1(mg)	4 - 6 hourly	15ml (6mg)
6-12 years	5ml (2mg)	4 - 6 hourly	30ml (12mg)
Adults and over 12 years	10ml (4mg)	4 - 6 hourly	60ml (24mg)
Elderly	10ml (4mg)	4 - 6 hourly	30ml (12mg)
Tablets			
12-17 years and adults	1 tablet (4mg)	4 - 6 hourly	6 tablets (24mg)
Elderly	1 tablet (4mg)	4 - 6 hourly	3 tablets (12mg)

Duration of treatment	For duration of symptoms but do not use for longer than 2 weeks without consulting GP

Quantity to be supplied (leave blank if PGD is administration ONLY)	Chlorphenamine syrup and tablets can be purchased OTC from registered pharmacies. A supply can be issued if further doses are required and the patient/carer does not have a supply at home or is unable to obtain a supply OTC. A supply should be made as follows • 1x 30 tablet TTO pack of chlorphenamine 4mg tablets OR • 1x 150ml bottle of chlorphenamine syrup 2mg/5ml with appropriate spoon or oral syringe 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. The following MUST be added to the labelled TTO packs before supply • Patient name • Date of supply • Issuing department • The dose indicated for the patient A prescription charge should be levied in clinical areas who are required to issue NHS prescription charges. Adult patients who pay for prescriptions may therefore prefer to consult a community pharmacist for a supply.
Storage	Stocks must be stored in a lockable medicine cupboard/trolley specifically reserve for such purpose according to UHDB Medicine policy and in conditions in line with SPC. • Do not store above 25 °C room temperature. • Store in the original package. • 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: • Concurrent use of chlorphenamine and hypnotics or anxiolytics may cause an increase in sedative effects therefore medical advice should be sought before taking • concurrent use of alcohol may have a sedative effect which may affect the ability to perform skilled tasks e.g. driving • Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity. • The anticholinergic effects of chlorphenamine are intensified by MAOIs A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website (see references)

Adverse reactions	The following side effects are common with Chlorphenamine: • Sedation, somnolence, impaired concentration • Abnormal coordination, dizziness, headache, blurred vision, nausea, dry mouth, fatigue • drowsiness A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website (see references)
Management of and reporting procedure for adverse reactions	• Assess patient using ABCDE and provide medical intervention appropriately. • Refer to ED or Medical Consultant immediately. • If Anaphylaxis occurs treat as per local emergency protocols and transfer to A&E via 999 if appropriate to area. • Use the MHRA Yellow Card scheme to report any suspected adverse reactions. Go to: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record • Complete incident report via UHDB Trust incident management system (Datix)
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	Inform the individual/carer of possible side effects and their management. Side effects could affect ability to drive and use machinery. The individual/carer should be advised to seek medical advice in the event of an adverse reaction.
Records	Record the following information on ePMA (Electronic Prescribing system) UHDB 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	• Electronic Medicines Compendium - Syrup https://www.medicines.org.uk/emc/product/3928/smpc accessed online 20/08/2024 • Electronic Medicines Compendium - Tablet https://www.medicines.org.uk/emc/product/3927/smpc accessed online 20/08/2024 • Electronic BNF https://bnf.nice.org.uk/drugs/chlorphenamine-maleate/ accessed online 20/08/2024 • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2

7. Registered health professional authorisation sheet

PGD Name [version]: QHB - ED/MIU/Ambulatory Care - Chlorphenamine Maleate Tablets and Syrup [v2]
PGD ref: UHDB119
Valid from: 28/11/2024 Expiry date: 27/11/2027

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.