

PATIENT GROUP DIRECTION (PGD)

**Administration of Chlorphenamine 10mg/ml Injection for skin symptoms caused by allergic reactions
By Registered Staff in All Adult UHDB services**

Documentation details

Reference no:	UHDB018
Version no:	1
Valid from:	16/08/2022
Review date:	16/02/2025
Expiry date:	15/08/2025

Change history

Version number	Change details	Date
1	New template – Extended for all UHDB staff on any site	

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
James Hooley	Medicines Safety Officer (Pharmacist)
Thomas Morley	Lead Medicines Information Pharmacist (Pharmacy Resus lead)
David Jones	UHDB Resuscitation & clinical skills manager
Core Adult PGD list maintained by Medicines Safety Group.	Note: No PGD working group convened as this PGD is created by merging detail from multiple authorised PGDs in active use across UHDB which have been developed previously with nursing and medical input.

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	-	-

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 staff providing UHDB services (includes UHDB staff/services undertaken on non-UHDB premises)

This is a core PGD and can be implemented in all adult services where training and resources have been allocated by senior staff to do so (see policy and limitations below if in doubt).

Limitations to authorisation

It is the responsibility of the practitioner working under this PGD to ensure that this PGD is in place in the area they are practising at the time of use. In most cases, this is implicit when a senior manager requests the staff to undertake training and then authorises them in section 7 of this document. However, when working in alternative areas (e.g. internal bank or redeployment) it is important that the practitioner confirms with a departmental manager in the new department that the core PGDs are in-use in their area.

Organisational Authorisation (legal requirement).

Role	Name	Sign	Date
Deputy Chief Pharmacist <i>Chief Pharmacist / Deputy</i>	Matt Prior	Signed copy held in Pharmacy	16/08/2022

Additional signatories (required as per legislation and locally agreed policy)			
Role	Name	Sign	Date
Medicines Safety Officer (pharmacist) <i>Clinical Pharmacist from PGD working group</i>	James Hooley	Signed copy held in Pharmacy	13/07/2022
Medical Director / Deputy <i>Doctor</i>	Dr James Crampton	Signed copy held in Pharmacy	18/07/2022
Chief Nurse / Deputy <i>Registered Professional representing users of the PGD</i>	Garry Marsh	Signed copy held in Pharmacy	10/08/2022

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	All Divisions, Adult Areas, 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	<ul style="list-style-type: none"> - 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
Competency assessment	<p>Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions</p> <p>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 either the authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.</p>
Ongoing training and competency	<p>Annual Medicines Safety Training (essential to role)</p> <p>Review/repeat initial training above when this PGD is revised</p> <p>Basic Life Support + AED + Anaphylaxis training</p> <p>Aseptic non-touch Technique (ANTT)</p>
<p><i>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.</i></p>	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	<p>As an option to treat skin symptoms that often occur as part of allergic reactions including anaphylaxis</p> <p>Note: Antihistamines have no role in treating respiratory or cardiovascular symptoms of anaphylaxis. Their use must not delay treatment of respiratory or cardiovascular symptoms of anaphylaxis (using adrenaline +/- IV fluids)</p>
Criteria for inclusion	<p>Patients who experience cutaneous/skin symptoms which often occur as part of allergic reactions including anaphylaxis</p> <p>Patients experiencing anaphylaxis must be cardiovascularly stabilised prior to considering antihistamines (prioritise adrenaline +/- IV fluids).</p> <p>Patients who require a parenteral antihistamine. Chlorphenamine should only be considered if a prescription or PGD is not suitable or available for a non-sedating oral antihistamine (cetirizine 1st line as per Resuscitation Council UK).</p>
Criteria for exclusion	<p>Patients under 16 years of age</p> <p>Cases of documented hypersensitivity to chlorphenamine.</p> <p>Patients treated with monoamine oxidase inhibitors (MAOIs) in the last 14 days,</p>
Cautions including any relevant action to be taken	<p>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.</p>
Action to be taken if the patient is excluded	<ul style="list-style-type: none"> • Refer to medical staff or prescriber for review of alternative pharmacological management. • Record reasons for exclusion in patient notes (retrospectively as soon as practicable following management of the emergency)
Action to be taken if the patient or carer declines treatment	<ul style="list-style-type: none"> • As above for excluded patients
Arrangements for referral for medical advice	<p>In cases of presumed anaphylaxis/cardiac arrest, follow your local medical emergency procedures (e.g. 2222 / 3333 / 999 procedures)</p>

5. Description of treatment

Name, strength & formulation of drug	Chlorphenamine Maleate 10mg Injection
Legal category	POM

Route / method of administration	By Intramuscular injection OR Slow (over 1 minute) Intravenous bolus injection if intravenous access is available.
Indicate any off-label use (if relevant)	n/a
Dose and frequency of administration	10mg by IM (or slow IV) injection ONCE ONLY
Duration of treatment	Single dose only under this PGD
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: <ul style="list-style-type: none"> • Store in original container to protect from light • Store below 25 degrees Celsius
Drug interactions	The following interactions may require additional consideration or monitoring following the administration: <ul style="list-style-type: none"> • 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 – See contraindications. <p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
Identification & management of adverse reactions	Common side effects include: Concentration impaired; coordination abnormal; dizziness; dry mouth; fatigue; headache; nausea; vision blurred
	Injection specific side effects include: central nervous system stimulation; confusional psychosis (in adults); dyspepsia; gastrointestinal disorder; hepatitis; sedation
	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	<ul style="list-style-type: none"> • 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. <p>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.</p>

<p>Written information to be given to patient or carer</p>	<p>None routinely given. If patient has questions, consider providing marketing authorisation holder's patient information leaflet (PIL) provided with the product or obtained via www.medicines.org.uk.</p>
<p>Patient advice / follow up treatment</p>	<p>Verbal advice to the patient on why drug administered, action of the drug. Inform patient of possible causes of the allergic reaction and any further management.</p> <p>In cases where anaphylaxis has occurred. Follow the UHDB clinical guideline and the PGD for anaphylaxis for further actions to take for post-anaphylaxis referral and management.</p>
<p>Records</p>	<p>For inpatients, the record of administration must be documented in the ePMA system or medicines chart used in your area.</p> <p>For other areas, an ePMA system should be used if in-use in your area as this will ensure all legal criteria are fulfilled and auditable.</p> <p>Otherwise, records can be made in the medical notes or within the patient pathway (e.g. in daycase or triage where a pathway booklet is in use) but must include the legal requirements below.</p> <p>Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following:</p> <ul style="list-style-type: none"> • 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 <u>supplied and/or administered</u> via Patient Group Direction (PGD) <p>Records should be signed and dated (or a password controlled e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>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.</p>

6. Key references

Key references	<ul style="list-style-type: none"> • <i>Electronic Medicines Compendium</i> http://www.medicines.org.uk/ • <i>Electronic BNF</i> https://bnf.nice.org.uk/ • <i>NICE Medicines practice guideline "Patient Group Directions"</i> https://www.nice.org.uk/guidance/mpg2 • Resus Council UK. Emergency treatment of anaphylaxis Guidelines for healthcare providers. May 2021. Accessed 15/02/2022 • <i>UHDB. Clinical Guideline - Anaphylaxis - Management of Suspected Anaphylaxis in Adults. Accessed 24/11/2021</i> Emergency Treatment of Anaphylaxis May 2021_0.pdf (resus.org.uk)
-----------------------	--

7. Registered health professional authorisation sheet

PGD Name [version]: Chlorphenamine 10mg/ml Injection for allergic skin reactions [v1.0]
PGD ref: UHDB018

Valid from: 16/08/2022

Expiry date: 15/08/2025

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.