

## PATIENT GROUP DIRECTION (PGD)

**Administration of oral Chlorphenamine maleate  
By Registered Nurses in Paediatric Services at UHDB**

### Documentation details

Reference no:	UHDB165
Version no:	1
Valid from:	04/05/2022*
Review date:	04/11/2024
Expiry date:	03/05/2025

### Change history

Version number	Change details	Date
1	New UHDB format PGD	21/03/2022

### 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
Jane Gadie	Emergency Nurse Practitioner
Julie Vanes	Senior Pharmacist, Paediatrics / Medicines Safety
Dr Gisela Robinson	Consultant Paediatrician

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
Registered Nurses working in Paediatric Areas at RDH and QHB (Ward areas both sites, Children's Emergency Department at RDH, Paediatric Assessment Unit at QHB) and in ED at QHB
Limitations to authorisation
Note that this is an administration-ONLY PGD for a single dose to be given. Any of the above areas needing to provide discharge packs will need to have/develop a supply-PGD to facilitate.

Organisational Authorisation (legal requirement).			
Role	Name	Sign	Date
Medicines Safety Officer  <i>Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)</i>	<b>James Hooley</b>	<b>Signed copy held in Pharmacy</b>	

Additional signatories (required as per legislation and locally agreed policy)			
Role	Name	Sign	Date
Paediatric Pharmacist <i>Clinical Pharmacist from PGD working group</i>	Julie Vanes	Signed copy held in Pharmacy	05/04/2022
Consultant Paediatrician <i>Doctor</i>	Dr Robinson	Signed copy held in Pharmacy	22/03/2022
Lead Nurse for Paediatrics <i>Registered Professional representing users of the PGD</i>	Laura Churm	Signed copy held in Pharmacy	22/04/2022

Local enquiries regarding the use of this PGD may be directed to [UHDB.PGDgovernance@nhs.net](mailto: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

<b>Qualifications and professional registration</b>	Registered Nurses working in Paediatric Areas at RDH and QHB (Ward areas both sites, Children's Emergency Department at RDH, Paediatric Assessment Unit at QHB) and in ED at QHB
<b>Initial training</b>	<ul style="list-style-type: none"> <li>- Completion of all Essential-to-role training as outlined in the UHDB PGD policy.</li> <li>- Individual has read and understood full content of this PGD and signed authorisation (section 7)</li> <li>- Completion of Medicines Management Drug Assessment</li> </ul>
<b>Competency assessment</b>	<p>Staff operating under this PGD are encouraged to review their competency using the <a href="#">NICE Competency Framework for health professionals using patient group directions</a></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 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.</p> <p>Approved drug assessment</p>
<b>Ongoing training and competency</b>	Knowledge of NICE anaphylaxis guidance
<p><b><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></b></p>	

#### 4. Clinical condition or situation to which this PGD applies

<b>Clinical condition or situation to which this PGD applies</b>	<p>Symptomatic relief of allergy such as hay fever, urticaria, food allergy, drug reactions, bites and stings</p> <p>Relief of itch associated with chickenpox</p>
<b>Criteria for inclusion</b>	<p>Children aged 1 – 18 years</p> <p>Syrup may be used for all ages Tablets can only be used for children aged 6 years and older (due to the product licence)</p>
<b>Criteria for exclusion</b>	<p>Children under the age of 1 year</p> <p>Dose of chlorphenamine given in the previous 6 hours Known hypersensitivity to chlorphenamine, anti-histamines or any of the ingredients in the preparation to be used Known galactose intolerance Patient takes phenytoin (risk of toxicity)</p>
<b>Cautions including any relevant action to be taken</b>	<p>Epilepsy Pyloroduodenal obstruction Susceptibility to angle-closure glaucoma Urinary retention</p>
<b>Action to be taken if the patient is excluded</b>	<ul style="list-style-type: none"> <li>• Record reasons for exclusion in patient notes</li> <li>• Advise patient on alternative treatment</li> <li>• Refer to a prescriber immediately</li> </ul>
<b>Action to be taken if the patient or carer declines treatment</b>	<ul style="list-style-type: none"> <li>• Document refusal and subsequent advice given</li> <li>• Advise patient on alternative treatment               <ul style="list-style-type: none"> <li>• Refer to a prescriber if appropriate</li> </ul> </li> </ul>
<b>Arrangements for referral for medical advice</b>	<p>Refer to the appropriate medical practitioner in the care pathway</p>

#### 5. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	<p>Chlorphenamine maleate 4mg tablets Chlorphenamine maleate syrup 2mg/5ml</p>
<b>Legal category</b>	<p>P (pharmacy medicine)</p>
<b>Route / method of administration</b>	<p>Oral</p>
<b>Indicate any off-label use (if relevant)</b>	<p>N/A</p>
<b>Dose and frequency of administration</b>	<p>Only ONE dose may be given on the PGD</p> <ul style="list-style-type: none"> <li>• 12-23 months: 1mg every 12 hours; maximum 2mg per day</li> <li>• 2-5 years: 1mg every 4-6 hours; maximum 6mg per day</li> <li>• 6-11 years: 2 mg every 4-6 hours; maximum 12 mg per day.</li> <li>• 12-17 years: 4 mg every 4-6 hours; maximum 24 mg per day</li> </ul>

<b>Duration of treatment</b>	One dose can be given as a PGD One dose lasts 4-6 hours
<b>Quantity to be supplied (leave blank if PGD is administration ONLY)</b>	
<b>Storage</b>	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below:
<b>Drug interactions</b>	<ul style="list-style-type: none"> <li>• Phenytoin – metabolism of this is inhibited by chlorphenamine, risk of increased phenytoin levels</li> <li>• Hypnotics or anxiolytics e.g. benzodiazepines, may increase sedative effects</li> <li>• MAOIs (a group of anti-depressant medicines) e.g. moclobemide, phenelzine, will increase anticholinergic effects</li> </ul> <p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
<b>Identification &amp; management of adverse reactions</b>	<p><b>Common side effects</b></p> <p>Drowsiness.</p> <p>Impaired concentration, abnormal co-ordination; dizziness; dry mouth; fatigue; blurred vision; nausea; headache</p> <p><b>Less common (frequency not known):</b></p> <p>Agitation; appetite decreased; blood disorder; bronchial secretion viscosity increased; depression; diarrhoea; haemolytic anaemia; hypotension; irritability; muscle twitching; muscle weakness; nightmare; palpitations; photosensitivity reaction; skin reactions; tinnitus; urinary retention; vomiting</p> <p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a></p>
<b>Management of and reporting procedure for adverse reactions</b>	<ul style="list-style-type: none"> <li>• 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: <a href="https://yellowcard.mhra.gov.uk">https://yellowcard.mhra.gov.uk</a></li> <li>• Record all adverse drug reactions (ADRs) in the patient's medical record.</li> <li>• 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</li> </ul>

	harm during clinical use.
<b>Written information to be given to patient or carer</b>	Verbal advice can be given at the time of administration. Patient information leaflet can be supplied if required – suitable leaflets available from <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> or Medicines for Children <a href="https://www.medicinesforchildren.org.uk/">https://www.medicinesforchildren.org.uk/</a> (this can also be accessed via BNFC)
<b>Patient advice / follow up treatment</b>	Verbal advice can be given at the time of administration and inform patient/carer not to repeat the dose within 4-6 hours
<b>Records</b>	<p>Record the following information on ePMA (Electronic Prescribing system) UHDB – currently MediTech or Lorenzo</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"> <li>• name of individual, address, date of birth and GP with whom the individual is registered (if relevant)</li> <li>• name of registered health professional</li> <li>• name of medication supplied/administered</li> <li>• date of supply/administration</li> <li>• dose, form and route of supply/administration</li> <li>• quantity supplied/administered</li> <li>• batch number and expiry date (if applicable e.g. injections and implants)</li> <li>• advice given, including advice given if excluded or declines treatment</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• Confirm whether <u>supplied and/or administered</u> and that this was done via Patient Group Direction (PGD)</li> </ul> <p>Records should be signed and dated (or a password controlled e-records). 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

<b>Key references</b>	<p><a href="https://bnf.nice.org.uk/drug/chlorphenamine-maleate.html">https://bnf.nice.org.uk/drug/chlorphenamine-maleate.html</a> [accessed 20 November 2021]</p> <ul style="list-style-type: none"> <li>• Electronic Medicines Compendium <a href="http://www.medicines.org.uk/">http://www.medicines.org.uk/</a> / ( accessed 17/12/2021)</li> <li>• Medicines for children <a href="https://www.medicinesforchildren.org.uk/">https://www.medicinesforchildren.org.uk/</a></li> <li>• NICE Medicines practice guideline “Patient Group Directions” <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> </ul>
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**7. Registered health professional authorisation sheet**

**PGD Name [version]: UHDB – Paediatrics – Chlorphenamine [v1]**  
**PGD ref: UHDB165**

**Valid from: 04/05/2022                      Expiry date: 03/05/2025**

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.

<b>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.</b>			
Name	Designation	Signature	Date

**Authorising manager / Assessor**

<b>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 &amp; Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.</b>			
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.