



**Scottish
Ambulance
Service**

Working in Partnership with Universities



Patient Group Direction PGD205

FOR THE ADMINISTRATION OR SUPPLY OF **CHLORPHENAMINE MALEATE**

Staff Grade:	Qualified and Year Two Trainee: Advanced Paramedic Practitioners Advanced Nurse Practitioners (Urgent and Primary Care)
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Document Author(s) / Owner	
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Division / Organisation Wide	Advanced Practice (Urgent & Primary Care) only

Health Care Professionals must be HCPC or NMC registered and authorised by name under this PGD before attempting to treat any patient according to it and have signed the relevant declaration.

Before using this PGD, healthcare professionals must ensure they are working within their scope of practice and be competent in the treatment of patients identified as suitable for inclusion under this PGD.

“Your scope of practice is the limit of your knowledge, skills and experience and is made up of the activities you carry out within your professional role. As a health and care professional, you must keep within your scope of practice at all times to ensure you are practising safely, lawfully and effectively. This is likely to change over time as your knowledge, skills and experience develop.” (HCPC 2024)

Staff should not deviate from their training, guidelines and scope of practice without taking professional clinical advice. All staff are expected to maintain their fitness to practice and undertake appropriate professional development to allow them to be fit for the role in which they are practising.

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1. Document Control Sheet

1.1 Key Information

Title:	Patient Group Direction PGD205
	Chlorphenamine Maleate
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1.2 Revision History

Version	Date	Summary of Changes	Name	Changes Marked
0.1	19/11/2024	Initial draft		N/A
1.0	26/03/2025	Updated to approved version no., guidance comments removed		Yes
1.0	01/05/2025	First issue – supersedes entry in PGD001a		Yes

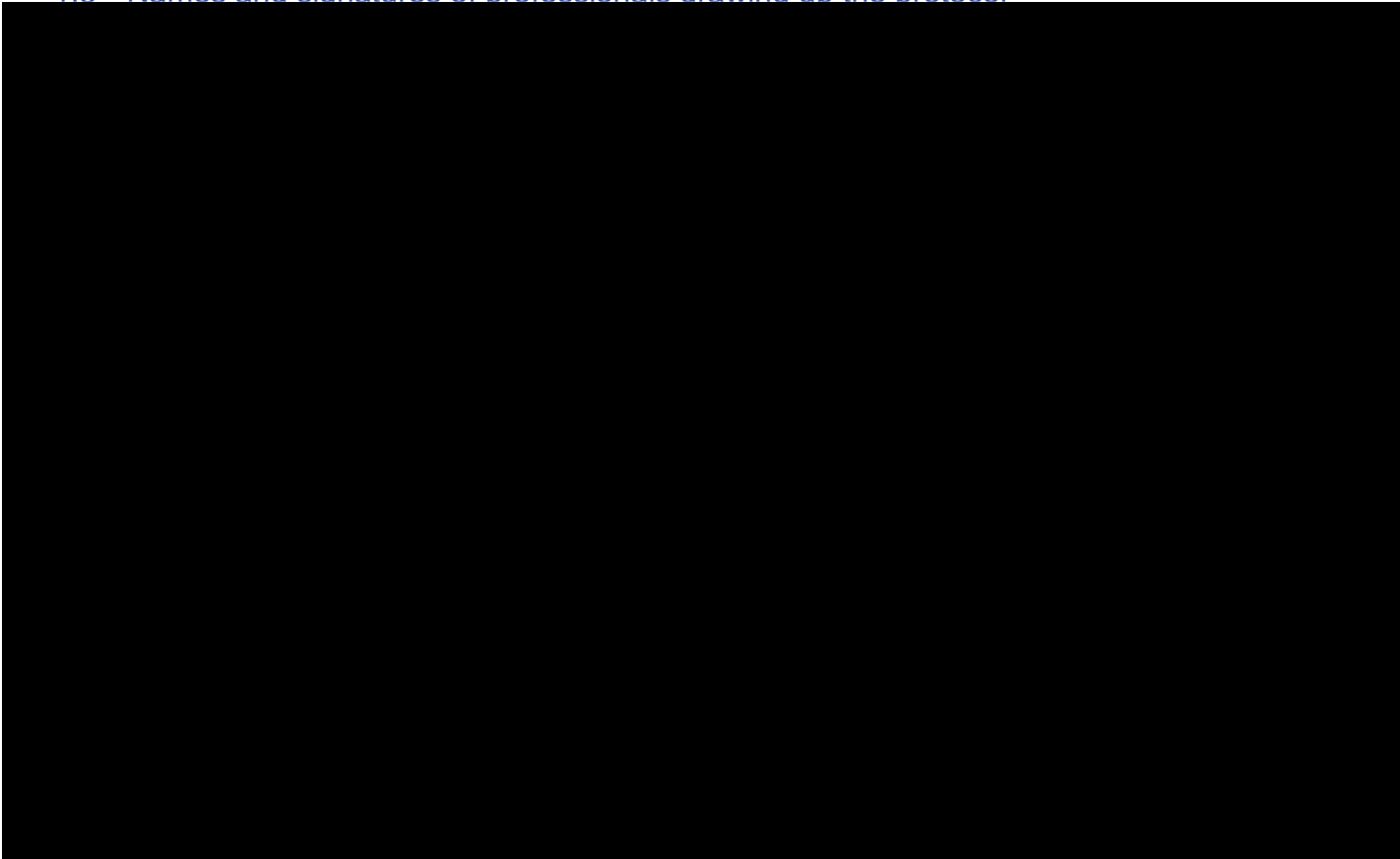
1.3 Approvals: This document requires the following approvals:

Name	Date	Version
National Advanced Practice Clinical Lead	30/01/2025	1.0
Medicines Management Group	30/01/2025	1.0
Pharmaceutical Advisor	03/03/2025	1.0
Medical Director	27/02/2025	1.0

1.4 Distribution: This document has been distributed to:

Name	Date	Version
Medicines Management Group	28/03/2025	1.0
Advanced Practice Leadership Team	28/03/2025	1.0
All Advanced Practitioners (UPC) & trainees	28/03/2025	1.0

1.5 Names and signatures of professionals drawing up the protocol



1.6 Professional / Advisory groups which have approved the protocol

Scottish Ambulance Service Medicines Management Group	Date	30/01/2025
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2. Using this PGD for Administration and/or Supply of Medicines

3. Characteristics of Staff

Qualifications required	Qualified and Year Two Trainee: Advanced Paramedic Practitioners Advanced Nurse Practitioners (in Urgent and Primary Care)
Specific or additional experience / training required	Undertaken an SCQF Level 11 module in Advanced Clinical Assessment (or equivalent) which included a period of supervised practice and signed off as competent. Passed all relevant written and practical assessments and ratified by a university exam board. Familiarisation with the signs and symptoms of conditions listed in “Criteria for Inclusion” in this PGD and possible differential diagnoses. Familiarisation with the use of Chlorphenamine, its indications, contra-indications and other details.
Continuing training requirements	The clinician should be aware of any changes to the evidence base for treatment conditions listed in “Criteria for Inclusion” in this PGD. The individual clinician is responsible for their own CPD and for keeping up to date with the use of medicine(s) in this PGD.
Other	You must be authorised by name under the current version of this PGD before you attempt to work to it

4. Clinical Situations / Conditions to Which the Patient Group Direction Applies

Definition of condition / situation to be treated	<ul style="list-style-type: none">• Symptomatic relief of mild to moderate allergic reactions:<ul style="list-style-type: none">○ Pruritus○ Urticaria○ Rhinitis○ Allergic reactions resulting in itch or inflammation e.g.:<ul style="list-style-type: none">▪ hay fever▪ insect bites▪ stings▪ food allergy• Relief of itch associated with chickenpox
Criteria for inclusion	Adults 16 years and over with any of the above condition / symptoms
Criteria for exclusion	<ul style="list-style-type: none">• Children under 16 years of age• Informed non-consent• Known allergy to Chlorphenamine or any excipients or ingredients in the preparation• Pregnancy or breastfeeding• Anaphylactic reactions where the allergen is unknown or cannot be isolated / removed – treat as per JRCALC guideline instead• Use of any Chlorphenamine-containing products within the last four hours, or the cumulative daily dose already taken – note that this excludes administration to the patient, they may still be supplied with Chlorphenamine for later use• Patients currently taking:<ul style="list-style-type: none">○ Any MAOI (or use within past 14 days)○ Clozapine• Significantly unwell patients requiring further assessment (blood tests, x-ray, etc.) or admission
Action if patient is excluded or declines treatment	Document in ePR / patient record. Discuss alternatives with patient / carer as appropriate and advise on risks of declining treatment. Consider referral to primary care or a community pharmacy. If necessary, consider referral or transfer to a suitable receiving unit.

5. Description of Treatment (including dosage and administration)

Name, form(s) and strength(s) of medicine	Chlorphenamine 4mg tablets
Legal status	P
Is the use outwith the SmPC?	No
Storage requirements	Room temperature
Route(s) / method(s) of administration	Oral administration only – may be taken with or without a drink
Dose and frequency of administration	All indications listed in this PGD: 4mg (one tablet) every 4-6 hours as required up to a maximum of 24mg (six tablets) in 24 hours
Maximum dose and number of treatments	As above. Maximum supply is one full box (normally 28 or 30 tablets depending on supply). If a patient has been treated with an intravenous or intramuscular Chlorphenamine injection under JRCALC guidance, they may also be supplied with tablets under this PGD but must not begin using them until at least 6 hours after the injection.

6. Cautions and Identification & Management of Adverse Reactions

Cautions	<p>Should be used with caution in:</p> <ul style="list-style-type: none">• Occupational drivers or machinery / plant operators (see advice below)• Patients already using regular antihistamines, or any other medicines which can cause sedation or CNS depression including opioid analgesics• Patients with chronic alcohol consumption• Epilepsy• Prostatic hypertrophy• Pyloroduodenal obstruction• Urinary retention• Angle-closure glaucoma <p>In some parts of the world (in particular North America) Chlorphenamine is known as Chlorpheniramine – clinicians should be aware of this when treating patients who live or are visiting from overseas, or have recently returned from overseas having used medicines there.</p>
Drug interactions	<p>May intensify the anticholinergic effects of some drugs, e.g. tricyclic antidepressants</p>
Identification and management of adverse reactions	<p>Anaphylactic reactions to Chlorphenamine are extremely rare and should be managed as per standard protocol / JRCALC guidance.</p> <p>Common or very common side-effects include: Blurred vision, Drowsiness or lethargy, Concentration and coordination impairments, Dizziness, Dry mouth, Headache, Nausea</p> <p>Elderly patients are more susceptible to side-effects.</p> <p>A detailed list of adverse reactions can be found in the product's SmPC and PIL, see references below.</p> <p>Any adverse reactions, and action taken, are recorded in the patient's notes and other appropriate documentation e.g.: clinical incident form, Yellow Card scheme, etc.</p>

7. Patient Advice and Documentation

Patient advice (verbal and written)	<ul style="list-style-type: none"> • Explain treatment plan and gain consent • Clinician should inform the patient / carer of the realistic timeframe for improvement of symptoms being treated • Must see medical practitioner if symptoms worsen or do not resolve within the expected timeframe • Advise patients that Chlorphenamine is likely to cause drowsiness and that if affected they should not drive or operate heavy plant or machinery • Advise that the patient <u>must not</u> take any other Chlorphenamine-containing products and that not all items are obvious that they contain Chlorphenamine. These include: <ul style="list-style-type: none"> ○ branded medicines such as Allerief, Hayleve, Piriton, Store or pharmacy-branded “allergy relief” tablets ○ liquid / suspension / syrup forms of the above ○ Galpseud Plus linctus • Advise to be especially cautious regarding any medicines purchased overseas which may include Chlorphenamine • Advise patients who take other regular antihistamines to stop them while using Chlorphenamine – in particular advise patients that using multiple different antihistamines does not increase the cumulative effect of them, but that it will increase the cumulative side-effects • Advise to avoid alcohol while taking Chlorphenamine • Advise to contact GP / nurse / pharmacist / out-of-hours service if side effects occur • Advised to call 999 if any life-threatening side-effects occur • It is not necessary to leave a copy of the manufacturer’s Patient Information Leaflet if only administering a single dose, but the patient / carer may be signposted to an electronic copy on EMC if requested • When provided with a supply of medications, patients should be given a copy of the manufacturer’s Patient Information Leaflet where available or signposted to an electronic copy if unavailable • Patients should be advised to maintain adequate hydration
Arrangements for referral to medical advice	Local arrangements apply
Additional facilities / supplies required	<p>Drinking water (if required).</p> <p>Chlorphenamine is also available in 2mg/5ml oral suspension which is not covered by this PGD.</p> <p><u>A single dose</u> of an oral Chlorphenamine tablet may be given to children between the ages of 6 and 16 years in accordance with the guidance in the JRCALC app, they <u>cannot</u> be administered or supplied under this PGD.</p>

	<p>If any of the above are required, refer to the patient's GP or a SAS prescriber.</p> <p>Chlorphenamine is in use in SAS as an 10mg/1ml vial for injection which is not covered by this PGD – refer to guidance on the JRCALC app.</p>
Monitoring	No specific monitoring required
Follow up	Patients having a first allergic reaction, or reacting to an unknown substance, should refer to their GP for allergy testing
Details of treatment records required	<p>The ePR, or other patient record, must contain the following:</p> <ul style="list-style-type: none"> • Name of the HCP using this PGD • Patient's name, address and date of birth. CHI number is also preferred • Name of medication and expiry date • Date and time of administration / supply • Dose (and volume if liquid preparation), form and route (and site if parenteral) of administration • If supplying medicine: <ul style="list-style-type: none"> ○ Dose and frequency to take ○ Number of items supplied • That it is administered and/or supplied under this PGD and not prescribed or via an exemption <p>The ePR, or other patient record, must also contain:</p> <ul style="list-style-type: none"> • The patient's medical and medication history • Medication and safety-netting / worsening advice given to the patient / carer <p>All records must be clear, legible and contemporaneous.</p>

8. References and Further Reading

NICE Medicines Practice Guideline MPG2: Patient group directions

[Overview](#) | [Patient group directions](#) | [Guidance](#) | [NICE](#)

Chlorphenamine in BNF

[Chlorphenamine Maleate](#) | [Drugs](#) | [BNF](#) | [NICE](#)

Chlorphenamine on EMC

[Chlorphenamine Maleate 4mg Tablets SmPC](#) ([medicines.org.uk](https://www.medicines.org.uk))

[Chlorphenamine Maleate 4mg Tablets Patient Information Leaflet](#) ([medicines.org.uk](https://www.medicines.org.uk))

BNF Treatment Summaries

[Antihistamines, allergen immunotherapy and allergic emergencies](#) | [Treatment summaries](#) | [BNF](#) | [NICE](#)

[Food allergy](#) | [Treatment summaries](#) | [BNF](#) | [NICE](#)

[Herpesvirus infections](#) | [Treatment summaries](#) | [BNF](#) | [NICE](#)

NICE Clinical Knowledge Summary/Summaries (CKS)

[Allergic rhinitis](#) | [Health topics A to Z](#) | [CKS](#) | [NICE](#)

[Insect bites and stings](#) | [Health topics A to Z](#) | [CKS](#) | [NICE](#)

[Chickenpox](#) | [Health topics A to Z](#) | [CKS](#) | [NICE](#)

[Food allergy](#) | [Health topics A to Z](#) | [CKS](#) | [NICE](#)

[Itch - widespread](#) | [Health topics A to Z](#) | [CKS](#) | [NICE](#)

[Urticaria](#) | [Health topics A to Z](#) | [CKS](#) | [NICE](#)

NICE Clinical Guidelines

[CG134 Anaphylaxis: Assessment and referral after emergency treatment](#) | [Guidance](#) | [NICE](#)

[CG183 Drug allergy: Diagnosis and management](#) | [Guidance](#) | [NICE](#)

Other Useful Links

[Chickenpox](#) | [NHS inform](#)

[Food allergy - Illnesses and conditions](#) | [NHS inform](#)

[Insect bites and stings](#) | [NHS inform](#)

[Itchy skin](#) | [NHS inform](#)

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