



## Patient Group Direction PGD218

### FOR THE ADMINISTRATION OR SUPPLY OF **HYOSCINE BUTYLBROMIDE**

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	
Version	1.0
Issue Date	28/03/2025
Review Date	28/03/2028
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.

## 1. Document Control Sheet

### 1.1 Key Information

<b>Title:</b>	Patient Group Direction PGD218 Hyoscine Butylbromide
<b>Date published / issued:</b>	28/03/2025
<b>Date effective from:</b>	01/05/2025
<b>Version / issue number:</b>	1.0
<b>Document type:</b>	Patient Group Direction
<b>Document status:</b>	Final
<b>Authors:</b>	
<b>Owner:</b>	
<b>Approver:</b>	Medicines Management Group
<b>Contact:</b>	
<b>Filename / location:</b>	TBA

### 1.2 Revision History

Version	Date	Summary of Changes	Name	Changes Marked
0.1	03/02/2024	Initial draft		N/A
0.2	12/02/2024	Revised and approved version at MMG		N/A
0.3	17/12/2024	Reorganised / reformatted for visual consistency with other UPC PGDs, minor content change only		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

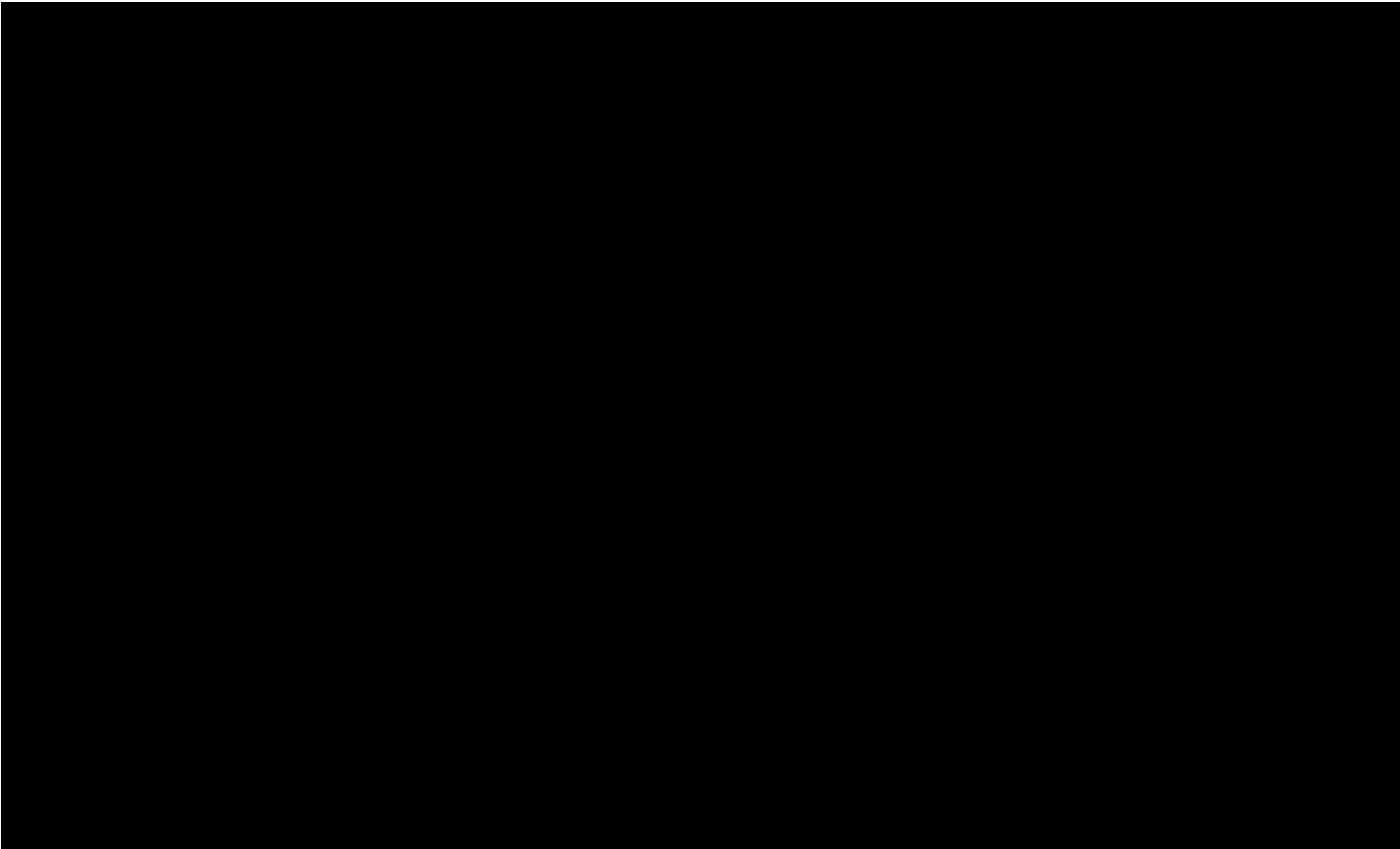
### 1.3 Approvals: This document requires the following approvals:

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

<b>Qualifications required</b>	Qualified and Year Two Trainee: Advanced Paramedic Practitioners Advanced Nurse Practitioners (in Urgent and Primary Care)
<b>Specific or additional experience / training required</b>	<p>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.</p> <p>Familiarisation with the signs and symptoms of conditions listed in “Criteria for Inclusion” in this PGD and possible differential diagnoses.</p> <p>Familiarisation with the use of Hyoscine butylbromide, its indications, contra-indications and other details in relation to palliative care.</p>
<b>Continuing training requirements</b>	<p>The clinician should be aware of any changes to the evidence base for treatment conditions listed in “Criteria for Inclusion” in this PGD.</p> <p>The individual clinician is responsible for their own CPD and for keeping up to date with the use of medicine(s) in this PGD.</p>
<b>Other</b>	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

<b>Definition of condition / situation to be treated</b>	Treatment of excessive thin upper respiratory secretions in palliative care, particularly in the last weeks or days of life
<b>Criteria for inclusion</b>	Adults 16 years and over at end of life and requiring symptomatic relief of distressing symptoms caused by excessive thin upper respiratory secretions
<b>Criteria for exclusion</b>	<ul style="list-style-type: none"> <li>• Children under 16 years of age</li> <li>• Informed non-consent</li> <li>• Known allergy / hypersensitivity to Hyoscine butylbromide or any excipients or ingredients in the preparation</li> <li>• Deep respiratory tract secretions that are not causing distress to the patient</li> <li>• Conscious patients complaining of dry mouth and/or mucous membranes</li> <li>• Gastrointestinal obstruction (mechanical or functional)</li> <li>• Hyperpyrexia (may reduce the ability to sweat)</li> <li>• Myasthenia gravis</li> <li>• Narrow angle glaucoma</li> <li>• Paralytic ileus</li> <li>• Pyloric stenosis</li> <li>• Significant bladder outflow obstruction</li> </ul>
<b>Action if patient is excluded or declines treatment</b>	<p>Document in ePR / patient record. Discuss alternatives with patient / carer as appropriate and advise on risks of declining treatment.</p> <p>Note that the exclusion criteria above are considered only theoretical in the provision of end-of-life care. Specialist advice from a local palliative care service should be sought urgently if untreated symptoms are causing the patient distress in an end-of-life event, or if there are any question regarding inclusion or exclusion criteria. Refer to local pathways listed in the JRCALC app. If ultimately necessary, consider referral or transfer to a suitable receiving unit.</p>

## 5. Description of Treatment (including dosage and administration)

Name, form(s) and strength(s) of medicine	Hyoscine butylbromide 20mg in 1ml ampoule for injection
Legal status	POM
Is the use outwith the SmPC?	Yes, however both the drug and the subcutaneous administration route are indicated for " <i>Excessive respiratory secretions in palliative care</i> " in the BNF and recommended in the NICE CKS for palliative care
Storage requirements	Room temperature.  Ampoules must be stored out of direct sunlight.
Route(s) / method(s) of administration	Subcutaneous injection
Dose and frequency of administration	<b>All indications listed in this PGD:</b> Single 20mg (1ml) SC bolus (undiluted). May be given up to hourly as required to a maximum of 120mg (six 20mg / 1ml doses) in 24 hours.  The patient may already be receiving a continuous subcutaneous infusion of Hyoscine butylbromide via syringe pump. In this instance, administer the prescribed breakthrough dose and contact the prescriber responsible for the maintenance of the subcutaneous infusion for further guidance.
Maximum dose and number of treatments	As above.  Injection ampoules must not be supplied to patients, relatives, carers, etc. under this PGD. If ongoing treatment will be required beyond the SAS clinician's involvement, contact with the patient's GP or local palliative care service should be made urgently for continued management of the patient. If this will cause an unacceptable delay in patient treatment, the clinician should seek support from a SAS prescriber.

## 6. Cautions and Identification & Management of Adverse Reactions

<b>Cautions</b>	<p>The following are listed as cautions in BNF and SmPC, however in the context of end-of-life care these are purely theoretical. If the clinician is concerned, they should discuss the case with a qualified AP or contact the local palliative care service:</p> <ul style="list-style-type: none"><li>• Acute myocardial infarction</li><li>• Arrhythmias (may be worsened)</li><li>• Autonomic neuropathy</li><li>• Cardiac insufficiency (due to association with tachycardia)</li><li>• Cardiac surgery (due to association with tachycardia)</li><li>• Conditions characterised by tachycardia</li><li>• Congestive heart failure (may be worsened)</li><li>• Coronary artery disease (may be worsened)</li><li>• Diarrhoea</li><li>• Elderly (especially if frail)</li><li>• Gastro-oesophageal reflux disease</li><li>• Hiatus hernia with reflux oesophagitis</li><li>• Hypertension</li><li>• Hyperthyroidism (due to association with tachycardia)</li><li>• Individuals susceptible to angle-closure glaucoma</li><li>• Prostatic hyperplasia</li><li>• Pyrexia</li><li>• Ulcerative colitis</li></ul>
<b>Drug interactions</b>	<p>The tachycardiac effects of beta-adrenergic agonists (e.g. Adrenaline, Formoterol, Salbutamol, Terbutaline) may be enhanced by Hyoscine butylbromide.</p> <p>Concomitant treatment with dopamine antagonists (e.g. Haloperidol, Domperidone, Metoclopramide) may result in diminution of the effects of both drugs on the gastrointestinal tract.</p> <p>Other drugs known to have antimuscarinic effects including medications for bladder problems, Parkinson's disease, other anti-emetics, anti-psychotics and bronchodilators.</p>
<b>Identification and management of adverse reactions</b>	<p><b>In patients with excessive secretions at the end of life, where secretions are deep within the respiratory tract, suctioning may worsen secretions.</b></p> <p><b>Patient's positioning and fluid balance should be optimised, for example stopping subcutaneous fluids and nursing the patient in a head-down or lateral position may help.</b></p> <p><b>Deeply unconscious patients at the end of life may have a particularly noisy respiratory pattern which causes concern to relatives and carers. Treatment with antimuscarinic drugs should only be administered when the patient themselves requires relief of symptoms caused by excessive respiratory secretions. An empathetic explanation of a</b></p>

**decision to administer or withhold Hyoscine butylbromide should be offered to relatives and carers.**

Anaphylactic reactions to Hyoscine butylbromide are extremely rare and should be managed as per standard protocol / JRCALC guidance.

Many drugs have antimuscarinic effects and concomitant use of two or more such drugs can increase side effects and lead to confusion in the elderly. Side effects include:

- Dry mouth
- Blurred Vision
- Urinary urgency and retention
- Dizziness
- Constipation
- Hypotension
- Transient bradycardia, followed by tachycardia
- Palpitations
- Flushing and dryness of skin
- Dyspnoea, which rarely occurs in patients with history of bronchial asthma and allergy

A detailed list of adverse reactions can be found in the product's SmPC and PIL, see references below.

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.



## 7. Patient Advice and Documentation

<b>Patient advice (verbal and written)</b>	<ul style="list-style-type: none"> <li>• Explain treatment plan and gain consent where applicable</li> <li>• Clinician should inform the patient / carer of the realistic timeframe for improvement of symptoms being treated</li> <li>• Must seek specialist palliative care advice if symptoms worsen despite treatment</li> <li>• Advise that Hyoscine butylbromide may cause drowsiness and if affected patients should not drive or operate any heavy plant or machinery</li> <li>• Elevation of intraocular pressure may be produced by the administration of anticholinergic agents such as hyoscine butylbromide with patients with undiagnosed (and therefore untreated) narrow angle glaucoma. Any change in vision following Hyoscine butylbromide injection should prompt the consideration of ophthalmological advice, if it would be considered beneficial to the patient's comfort</li> <li>• Advise to contact GP / nurse / pharmacist / out-of-hours service if side effects occur</li> <li>• Advise to call 999 if any life-threatening side-effects occur</li> <li>• It is not necessary to leave a copy of the manufacturer's Patient Information Leaflet if only administering medication, but the patient / carer may be signposted to an electronic copy on EMC if requested</li> </ul>
<b>Arrangements for referral to medical advice</b>	<p>Patients with unmanaged distressing symptoms at the end of life should be referred urgently to their GP or a palliative care specialist for further input. Where anticipatory medicines / JiC have been administered, the patient's district or palliative care nurse should be updated to ensure repeat doses are accessible; it is essential to ensure that a prescription and supply of any medications likely to be required has been arranged</p>
<b>Additional facilities / supplies required</b>	<ul style="list-style-type: none"> <li>• 70% alcohol pre-injection swab(s)</li> <li>• 1ml syringe(s)</li> <li>• Blunt-fill filter needle(s)</li> <li>• 25G x 16mm (orange) needle(s)</li> <li>• 0.9% sodium chloride flush (if giving via a Saf-T or similar)</li> <li>• Sharps disposal box</li> <li>• Saf-T-Intima subcutaneous cannula (only where the clinician has been appropriately trained to insert this)</li> </ul> <p>Hyoscine butylbromide is also available in oral tablets which are not suitable for use in situations covered by this PGD.</p> <p>Hyoscine butylbromide ampoules can be administered intramuscularly or intravenously, but these are not suitable routes for use with palliative care patients.</p>
<b>Monitoring</b>	<p>No specific monitoring required</p>

<b>Follow up</b>	Any follow-up required would be via patient's GP or palliative care service
<b>Details of treatment records required</b>	<p>The ePR, or other patient record, must contain the following:</p> <ul style="list-style-type: none"> <li>• Name of the HCP using this PGD</li> <li>• Patient's name, address and date of birth. CHI number is also preferred</li> <li>• Name of medication and expiry date</li> <li>• Date and time of administration / supply</li> <li>• Dose (and volume if liquid preparation), form and route (and site if parenteral) of administration</li> <li>• If supplying medicine: <ul style="list-style-type: none"> <li>○ Dose and frequency to take</li> <li>○ Number of items supplied</li> </ul> </li> <li>• That it is administered and/or supplied under this PGD and not prescribed or via an exemption</li> </ul> <p>The ePR, or other patient record, must also contain:</p> <ul style="list-style-type: none"> <li>• The patient's medical and medication history</li> <li>• Medication and safety-netting / worsening advice given to the patient / carer</li> </ul> <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](#)

### **Hyoscine butylbromide in BNF**

[Hyoscine butylbromide](#) | [Drugs](#) | [BNF](#) | [NICE](#)

### **Hyoscine butylbromide on EMC**

[Hyoscine butylbromide 20mg in 1ml Ampoule for Injection SmPC \(medicines.org.uk\)](#)

[Hyoscine butylbromide 20mg in 1ml Ampoule Patient Information Leaflet \(medicines.org.uk\)](#)

### **BNF Treatment Summaries**

None relevant

### **NICE Clinical Knowledge Summary/Summaries (CKS)**

[Palliative care - secretions](#) | [Health topics A to Z](#) | [CKS](#) | [NICE](#)

### **NICE Clinical Guidelines**

[CSG4 Improving supportive and palliative care for adults with cancer](#) | [Guidance](#) | [NICE](#)

### **Other Useful Links**

[Anticipatory prescribing](#) | [Right Decisions](#)

[Palliative care](#) | [NHS inform](#)

['Just in case' medicines in palliative care](#) | [NHS inform](#)