

Use of Medicines Outside of their UK Marketing Authorisation in Palliative Medicine

Prescribing for Off-Label Indications or Unlicensed Medicines

TARGET AUDIENCE	Board-wide – Information for Professionals
PATIENT GROUP	Palliative Medicine Patients

Summary

Patients with palliative care needs may be prescribed drugs that are unfamiliar to non-specialist prescribers. In specialist palliative care up to one quarter of medicines are prescribed off-label or as unlicensed medicines.^{1,2} This document provides reference tables for off-label and unlicensed medications commonly prescribed in palliative care. This further information on the use of medicines outside of their marketing authorisation is to guide the non-specialist and to ensure they are fully informed, practicing safe prescribing and able to explain to patients and their families where appropriate.

Local Policy

Please refer to the [NHS Lanarkshire Unlicensed Medicines Policy](#) for information on unlicensed medicines, off-label use of licensed medicines and the corresponding responsibilities of prescribers and pharmacy. Section 10 relates to Palliative Care.

References

1. Atkinson C and Kirkham S (1999) Unlicensed uses for medication in a palliative care unit. *Palliative Medicine*. 13: 145– 152.
2. Todd J and Davies A (1999) Use of unlicensed medication in palliative medicine. *Palliative Medicine*. 13: 466.

Reference tables for off-label and unlicensed medications commonly prescribed in palliative medicine

- ❖ Please note these tables are for reference only and provide limited information on the medications listed.
- ❖ Adapted from the following resources
 - Scottish Palliative Care Guidelines
<https://rightdecisions.scot.nhs.uk/scottish-palliative-care-guidelines/>
 - Palliative Care Formulary and BNF
<https://www.medicinescomplete.com/#/>
- ❖ These tables are not exhaustive.
- ❖ Please follow best prescribing practice and ensure you are fully informed prior to prescribing.
- ❖ Code – **yellow = off label** and **blue = unlicensed**

Respiratory

Drug	Route	Indication
Dexamethasone Prednisolone	Oral or parental	SVCO, lymphangitis or tumour-associated airway obstruction, stridor
Immediate Release, Modified Release Morphine sulfate	Oral	SOB, cough suppressant
Morphine sulfate	SC	SOB
Lorazepam	Sublingual route of oral tablets	Anxiety and panic associated with severe breathlessness
Midazolam	SC	Anxiety and panic associated with severe breathlessness
Sodium chloride 0.9%	Inhalation of nebulised solution	Expectoration

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Nausea and Vomiting

Drug	Route	Note
Haloperidol	Oral/SC/CSCI	
Levomepromazine	SC/CSCI The injection solution can be administered by the off-label sublingual or buccal route.	
Dexamethasone	Oral/SC	Refractory nausea and vomiting
Metoclopramide	Oral/SC	Also off-label for delayed gastric emptying, functional dyspepsia, gastro-oesophageal reflux
Domperidone	Oral	MHRA small increased risk of serious cardiac side effects. Use lowest dose possible for ideally under 1 week and check for interactions. Also off-label for delayed gastric emptying, functional dyspepsia, gastro-oesophageal reflux

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Pain

Drug	Indication/note
Clonazepam (tablets, oral solution)	Neuropathic pain
Matrix fentanyl patches	Matrix patch formulation can be cut diagonally (unlicensed procedure) (Reservoir patch formulations must not be cut)
Lidocaine plasters	Neuropathic pain; Bone pain (authorised for postherpetic neuralgia)
Ketamine Injection	Pain unresponsive to standard treatments, including neuropathic, inflammatory, ischaemic limb and procedure-related pain SC route
IR hydromorphone oral solution	*Special medicine
Alfentanil spray 140microgram/spray, 5mg in 5ml bottle for buccal or intranasal use	'Special' medicine
Ketamine oral solution	*Special medicine
Clonazepam injection	Unlicensed in the UK. Imported.

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Seizure

Drug	Route	Indication
Buccolam® and Epistatus® oromucosal solution (midazolam)	Buccal	Seizures Not licensed for use in adults
Levetiracetam	CSCI	Monotherapy of generalised seizures
Midazolam	SC/CSCI	Seizures

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Bleeding

Drug	Route	Indication
Midazolam	IV/IM	Massive terminal haemorrhage
Diazepam	IV/rectal solution	Massive terminal haemorrhage
Buccolam [®] or Epistatus [®]	Buccal midazolam liquid sublingually	Massive terminal haemorrhage
Tranexamic acid	Paste (tablets crushed in base), aqueous solution, oral, mouthwash	Bleeding from skin or mucous membranes Chronic ischaemic radiation proctocolitis Bleeding from respiratory, urinary and GI tracts
Adrenaline	Topical	Bleeding from skin or mucous membranes
Sucralfate	Oral, rectal, paste	Bleeding from skin, mucous membranes, oesophagus
Desmopressin	IV/SC/Intranasal	Bleeding from skin or mucous membranes
Predsol [®]	Enema	Acute rectal mucosal damage following radiotherapy

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Emergencies and Miscellaneous

Drug	Indication
Dexamethasone	MSCC, SVCO, Raised intracranial pressure (ICP), stridor breathlessness (lymphangitis or tumour associated airway obstruction, anorexia, hiccups, obstruction of hollow viscus, refractory N+V
Ondansetron	Raised intracranial pressure (ICP)
Midazolam	Stridor Sedative/anxiolytic in terminal haemorrhage or agitation at the end of life Spasticity or skeletal muscle spasm Persistent hiccups Anxiety/panic e.g. in severe breathlessness at end of life – seek specialist advice Alcohol withdrawal at end of life Agitation in the imminently dying
Phenobarbital Haloperidol	Terminal agitation
Clonazepam	Neuropathic pain, restless legs, terminal restlessness, anxiety and panic attack

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Mouthcare

Drug	Indication
Carmellose paste (Orabase®)	Painful mouthcare
Lidocaine ointment (5%) or spray (10%)	Painful mouthcare
Water-based gel	Dry lips
Glycopyrronium bromide oral dose (as oral solution) Hyoscine hydrobromide transdermal patch or tablets Amitriptyline	Sialorrhoea Sialorrhoea
Atropine 1% eye drops on the tongue or sublingually	Sialorrhoea

Hiccups

Drug
Peppermint water
Antacids Altacite Plus® or Maalox Plus®
Nifedipine
Baclofen
Domperidone or metoclopramide
Dexamethasone
Midazolam

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Anorexia/cachexia

Drug	Route
Dexamethasone or Prednisolone	Oral
Megestrol acetate	Oral
Metoclopramide or Domperidone	Oral/SC/CSCI Oral

Bowel Obstruction

Drug	Route	Indication
Metoclopramide	SC	Peristaltic failure
Docusate sodium	Oral	Mechanical obstruction
Dexamethasone	SC	Mechanical obstruction
Hyoscine butylbromide	SC/CSCI	Vomiting

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Sweating

Drug

Paracetamol

Non-steroidal anti-inflammatory drug (NSAID)

Amitriptyline

Cimetidine

Venlafaxine

Hormone replacement therapy

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Itch

Drug
Rifampacin
Sertraline
Gabapentin
Naltrexone
Mirtazipine
Prednisolone
Cimetidine
Ondansetron
Paroxetine
Capsaicin 0.025% cream
Lidocaine Patches

Just in case (JIC) medications

Drug	Indication
Hyoscine Butylbromide Glycopyrronium Bromide	Secretions

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Unlicensed prescribing examples

- Mixing of licensed preparations of drugs in a syringe pump renders them unlicensed.
- An unlicensed route of administration.
- Medicinal products made in a local pharmacy at the request of a prescriber for an individual patient, e.g. dilution of a cream.
- Continuation of an investigational product after a clinical trial ends.
- ‘Specials’, e.g. special-order manufactured formulations made in the UK by a manufacturer with a specials manufacturing licence (MS) and medicinal products that require importation.

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Appendices

1. Governance information for Guidance document

Lead Author(s):	Dr Beth Goundry, Specialty Doctor in Palliative Medicine
Endorsing Body:	Specialist Palliative Care Drugs and Therapeutics Group and Area Drugs and Therapeutics Committee
Version Number:	1.0
Approval date	April 2024, ADTC
Review Date:	April 2027
Responsible Person (if different from lead author)	Linda Johnstone

CONSULTATION AND DISTRIBUTION RECORD	
Contributing Author / Authors	Linda Johnstone, Macmillan Area Lead Pharmacist-Palliative Care
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Distribution	NHS Lanarkshire Guidelines Website

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CHANGE RECORD			
Date	Lead Author	Change	Version
		<i>e.g. Review, revise and update of policy in line with contemporary professional structures and practice</i>	1
			2
			3
		.	4
			5

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