University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of Flumazenil 100mcg/ml By Nurse Endoscopists in Endoscopy at Royal Derby, Queens Burton & Sir Robert Peel Hospitals

Documentation details

Reference no:	UHDB 122
Version no:	1
Valid from:	03/11/2021
Review date:	03/05/2024
Expiry date:	02/11/2024

Change history

Version number	Change details	Date
1	New template used to cover multiple sites (replaces legacy QHB and RDH PGDs)	01/07/21

Glossary

Abbreviation	Definition
HEE	Health Education England
JAG	Joint advisory Group on GI Endoscopy

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
Dr Stephen Hearing	Endoscopy Lead/ Consultant Gastroenterologist
James Kerr	Divisional Pharmacist
Scott Mackenzie	Lead Nurse Endoscopist

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
Endoscopy Unit at the Royal Derby Hospital, Endoscopy Unit at the Queens Hospital Burton, Endoscopy Unit at Sir Robert Peel Community Hospital
Limitations to authorisation
This organisation only authorises the use of this PGD by Nurse Endoscopists signed off as being fully competent endoscopy practitioners.

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer	James Hooley	**Signed copy held in Pharmacy**	**03/11/2021**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Divisional Pharmacist	James Kerr	**Signed copy held in Pharmacy**	**03/11/2021**
Endoscopy Lead/ Consultant Gastroenterologist	Dr Stephen Hearing	**Signed copy held in Pharmacy**	**23/10/2021**
Lead Nurse Endoscopist	Scott Mackenzie	**Signed copy held in Pharmacy**	**26/10/2021**

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	• NMC registered Nurse • JAG or HEE accredited Nurse Endoscopist
Initial training	• 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 • Completion of JAG Upper or Lower GI Endoscopy training
Competency assessment	Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions 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.
On-going training and competency	• Ongoing endoscopist training with annual CPD and appraisals. • ILS/ALS life support training competences. • Regular training to maintain and update all induction modules. • IV/ Cannulation training.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	All patients age 16 years and over undergoing endoscopic procedures, who require the reversal of the sedative effects of Benzodiazepines (i.e. Midazolam), not identified within the exclusion criteria below.
Criteria for inclusion	All patients aged 16 years and over, who require the reversal of the sedative effects of Benzodiazepines (i.e. Midazolam), not identified within the exclusion criteria below.
Criteria for exclusion	Patients with the following: • Known Flumazenil sensitivity/ allergy • Patients receiving benzodiazepines for control of a potentially life-threatening condition (e.g. control of intracranial pressure or status epilepticus). Patients who are: • Under 16 years of age • Pregnant • Breast feeding
Cautions including any relevant action to be taken	Patients with the following: • Benzodiazepine dependence • Patients with hepatic impairment • History of panic or anxiety disorders • Patients suffering from epilepsy receiving benzodiazepine treatment • Patients with a severe brain injury • Patients on any of the medication mentioned in the drug interaction section below. This is not an exhaustive list – please refer to BNF for further information if required.
Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes • Advise patient on alternative treatment
Action to be taken if the patient or carer declines treatment	• Document details and advice given in patient notes • Advise patient on alternative treatment
Arrangements for referral for medical advice	• A member of the medical team will always be in the endoscopy department and if on some rare occasion they are not, the medical registrar/consultant on call will be available. • Document details and advice given.

5. Description of treatment

Name, strength & formulation of drug	• Flumazenil, 100mcg/ml (5ml ampoules)
Legal category	• Prescription-only medicine (POM)

Route / method of administration	• Intravenous
Indicate any off-label use (if relevant)	• N/A
Dose and frequency of administration	• 200microgram dose to be administered over 15 seconds, then 100 micrograms every 1 minute if required • Usual dose 300–600 micrograms • Maximum 1000 micrograms per course
Duration of treatment	• Titrated as above to achieve conscious sedation reversal during or after endoscopy procedure.
Quantity to be supplied (leave blank if PGD is administration ONLY)	• N/A
Storage	Stock must be securely stored according to UHDB medicines policy in a drug cupboard and in conditions in line with SPC as detailed below: • Store in the original package in order to protect from light. • Use immediately once drawn up • Do not store above 25 degrees Celsius • Do not freeze
Drug interactions	Particular caution is only necessary when using flumazenil in cases of accidental overdose since the toxic effects of other psychotropic medicinal products (especially tricyclic antidepressants) taken concurrently may increase with the reduction of the benzodiazepine effect.
Identification & management of adverse reactions	Immune systems reactions including: • Allergic reactions • Anaphylactic reactions Psychiatric reactions including: • Anxiety • Emotional Lability • Insomnia • Somnolence • Fear • Withdrawal symptoms i.e. agitation, confusion, sensory disorders, tachycardia, dizziness, sweating, abnormal crying, aggressive behaviour Nervous system reactions including: • Vertigo • Headache • Agitation • Tremor • Dry Mouth • Hyperventilation • Speech disorders • Paraesthesia • Convulsions

	Other reactions: • Diplopia • Strabismus • Lacrimation increased • Abnormal hearing • Palpitations • Tachycardia or Bradycardia, extrasystole • Flushing • Hypotension • Orthostatic hypotension • Transient increased blood pressure on awakening • Dyspnoea • Cough • Nasal congestion • Chest pain • Nausea • Vomiting • Sweating • Injection site pain • Shivering Severe reactions: • There is very limited experience of acute overdose in humans with flumazenil. • There is no specific antidote for overdose with Flumazenil. Treatment should consist of general supportive measures including monitoring of vital signs and observation of the clinical status of the patient. In the event of anaphylactic shock or cardiac or respiratory arrest emergency help should be summoned immediately. Serious or unusual adverse reactions that could be attributed to the drug should be reported to a doctor, and a yellow card and incident form should be completed and submitted as appropriate.
Management of and reporting procedure for adverse reactions	• 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. • 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.
Written information to be given to patient or carer	• N/A
Patient advice / follow up	Inform the individual/carer of extremely low risk of any side effects

treatment	due to: • Elimination of Flumazenil being rapid, with a short half-life of 40 to 80 minutes • The intake of food during the intravenous infusion of flumazenil results in an increase of 50% of the clearance • The individual/carer should be advised to seek medical advice in the event of an adverse reaction.
Records	The following must be recorded in the patients endoscopy Medical record/notes by the healthcare practitioner working under this PGD: • 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 administered • Date of supply/administration • Dose, form and route of administration • Quantity supplied/administered • Batch number and expiry date (if applicable e.g. injections and implants) • Details of any adverse drug reactions and actions taken • Confirm whether administered via Patient Group Direction (PGD) • Records should be signed and dated • All records should be clear, legible and contemporaneous.

6. Key references

Key references	• Electronic Medicines Compendium: https://www.medicines.org.uk/emc/product/6300 • Electronic BNF: https://bnf.nice.org.uk/drug/flumazenil.html • NICE Medicines practice guideline: "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • BSG: https://www.bsg.org.uk/wp-content/uploads/2019/12/AOMRC-guideline-on-safe-sedation-practice-for-healthcare-procedures.pdf

7. Registered health professional authorisation sheet

PGD Name [version]: Endoscopy - Flumazenil [v1] PGD ref: UHDB 122
Valid from: 03/11/2021 Expiry date: 02/11/2024

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.