University Hospitals of Derby and Burton
NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of Diazepam Rectal Solution

By registered Nurses, Emergency Nurse Practitioners (ENP) and Emergency Care Practitioners (ECP)

In Emergency Department and Same Day Emergency Care at Queens Hospital, Burton and Minor injuries departments at Samuel Johnson and Sir Robert peel community hospitals

Documentation details

Reference no:	UHDB103
Version no:	V2
Valid from:	28/11/2024
Review date:	28/05/2027
Expiry date:	27/11/2027

Change history

Version number	Change details	Date
1	Use of new UHDB template	May 2021
2	Adult dosing change: 10-20mg per dose reduced to 10mg in keeping with Trust Adult Status Epilepticus guidance and community hospital status guidance. Children's doses left as per BNFc and CEWT dosing.	October 2024

Glossary

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 Venkata Thungala	Consultant Emergency Medicine
Nida Halim	Pharmacist
Nadine Watson	Emergency Nurse Practitioner

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

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
In Emergency Department and Ambulatory care at Queens Hospital Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community Hospitals
Limitations to authorisation
For listed professions only: Registered Nurses, Emergency Nurse Practitioners (ENP) and Emergency Care Practitioners (ECP)

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medication Safety Officer *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	James Hooley	**Signed copy held by Pharmacy**	**28/11/2024**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Pharmacist *Clinical Pharmacist from PGD working group*	**Nida Halim**	**Signed copy held by Pharmacy**	**01/11/2024**
Lead ED Consultant *Doctor*	**Dr Venkata Thungala**	**Signed copy held by Pharmacy**	**14/11/2024**
Senior ENP *Registered Professional representing users of the PGD*	**Nadine Watson**	**Signed copy held by Pharmacy**	**29/10/2024**

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	Registered Nurses, Emergency Nurse Practitioners (ENP) and Emergency Care Practitioners (ECP) with professional registration working within their usual scope of practice who have a current contract with UHDB.
Initial training	• Completion of all Essential-to-role training as outlined in the UHDB PGD policy including core PGD training. • Individual has read and understood full content of this PGD and signed authorisation (section 7) • Completion of Medicines Management Drug Assessment
Competency assessment	Registered nurses, ENPs and ECPs with a current registration who are deemed competent by their line manager to undertake the clinical assessment of a patient leading to a diagnosis that requires treatment according to the indications listed in this PGD and Trust clinical guidelines for: • Prolonged Convulsive Epileptic Seizures or Convulsive Status Epilepticus (UHDB paediatric guideline – see references). 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 either the 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	• Annual Medicines Safety Training (essential to role) • Review/repeat initial training above when this PGD is revised • It is the responsibility of the registered practitioner to keep up to date with any change to the recommendations for diazepam rectal solution. • The registered healthcare practitioner will ensure anaphylaxis/ CPR training is kept updated yearly. • The registered healthcare professional must actively take part in CPD and annual individual performance reviews. • Regular training and updating in safeguarding children and vulnerable adults as per trust policy
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	• Prolonged febrile convulsions • Epileptic convulsions in known epileptics
Criteria for inclusion	Adult or child over 1 month presenting with repeated (recur in rapid succession without time for full recovery in between) or prolonged convulsions (>5 minutes and still fitting)
Criteria for exclusion	• Respiratory depression • Patients under 1 month of age. • Previous local or systemic reactions to the medicine • Known hypersensitivity to the active ingredient or to any component of the product – see section 6.1 on SPC Diazepam RecTubes 5mg Rectal Solution - Summary of Product Characteristics (SmPC) - (emc) (see references) • Pulmonary insufficiency, severe respiratory insufficiency • Sleep apnoea syndrome • Marked neuromuscular respiratory weakness and CNS depression • Compromised airway • Hyperkineses • Severe hepatic impairment (if known – do not need to take bloods prior to treatment) • Myasthenia gravis • Phobic or obsessional states • Organic brain changes, particularly arteriosclerosis • Patients taking clozapine • There is no evidence to the safety of diazepam in human pregnancy. It should not be used, especially during the first and last trimesters, **unless** the benefit outweighs the risk
Cautions including any relevant action to be taken	• Recent doses given by carers, relatives or ambulance crew should be considered when calculating the cumulative dose • Use with caution in patients with known* liver or renal impairment and in elderly or debilitated patients as elimination is prolonged. Dosage should initially be reduced to one half of the normal recommendation. ○ No requirement to await bloods if none available. • Use with caution if alcohol, opioids, antidepressants or other CNS depressants have been taken as side effects more likely. Close observation required until full recovery from sedation. • Safeguarding and chaperoning (refer to trust policy - see references) • Present in breast milk, avoid during breast feeding UNLESS benefit out-weighs the risks • ALL patients who have received rectal diazepam should be referred for medical advice • Transfer patient to hospital or GP with written confirmation of dose, time and route of administration. • Patient with muscle weakness

Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes • Advise patient on alternative treatment • Refer to a prescriber if appropriate • Arrange transfer to Emergency Department or call 999 if appropriate
Action to be taken if the patient or carer declines treatment	• Document advice given • Advise patient on alternative treatment • Refer to a prescriber if appropriate • Arrange transfer to Emergency Department or call 999 if appropriate
Arrangements for referral for medical advice	Refer to the appropriate medical practitioner in the care pathway. Transfer to Emergency Department or call 999 if appropriate

5. Description of treatment

Name, strength & formulation of drug	Diazepam rectal solution Strength : 5mg/2.5ml (2mg/ml) or 10mg/2.5ml (4mg/ml)
Legal category	Prescription-only Medicine (POM) CD schedule 4
Route / method of administration	For rectal administration only. Tubes are for single use only. The foil should be removed only before use. The solution is administered rectally. Adults should be in the lateral position; children should be in the prone or lateral position. a) Tear open the foil pack. Unscrew the cap and remove. b) Insert the tube nozzle completely into the rectum. For children under 15 kg, insert only half way. Hold the tube with the spout downwards. The contents of the tube should be completely emptied by using firm pressure with the index finger and thumb. c) To avoid suction, maintain pressure on the tube until it is withdrawn from the rectum. Press together the patient's buttocks for a short time
Indicate any off-label use (if relevant)	Diazepam Desitin®, Diazepam Rectubes®, and Stesolid Rectal Tubes® not licensed for use in children under 1 year. * Use in children from 1 month to 1 year is common in practice and dosages are given in BNF/BNFc * Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence. *See References
Dose and frequency of administration	• **CHILD- 1 month to 1 year**: 5mg for one dose then 5mg 10 minutes later if required • **CHILD- 2-11 years**: 5-10mg for one dose then 5-10mg 10 minutes later if required • **CHILD- 12-17 years**: 10mg for one dose then 10mg 10 minutes

	later if required (maximum 20mg cumulative as per UHDB paediatric guideline) • **ADULTS**: 10mg then 10mg after 10-15 minutes if required • **ELDERLY/DEBILITATED PATIENTS**; 5mg then 5mg after 10-15 minutes if required
Duration of treatment	Dose may be repeated after 10 minutes if required and if within maximum cumulative doses. Maximum of 2 doses
Quantity to be supplied	N/A
Storage	Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website Do not store above 25 °C. Store in original package in order to protect from light. Short-term exposure to higher temperatures (e.g. in emergencies), is of no consequence
Drug interactions	**Drug interactions are unlikely after a single dose of rectal diazepam. However, the following drugs may interact, therefore it is advisable to monitor patient.** Enhanced CNS depression if patient has had other CNS depressants including alcohol and opioids (+ respiratory depressions with opioids) including; • Anxiolytics • Sedatives, hypnotics, anaesthetics • Anti-epileptics • Sedative antihistamines • Antidepressants **The following interactions have been identified and should be considered where a patient is on the following medicines:** **Fluconazole, Fluvoxamine, Voriconazole** Moderately increases exposure to diazepam **Tocilizumab, Etravirine, Idelalisib, Ritonavir** Predicted to increase exposure to Diazepam **Fosphenytoin, Phenytoin** Diazepam potentially affects concentration of these drugs **Clozapine** Pharmacodynamic synergism. Severe hypotension, respiratory depression, unconsciousness and potentially fatal respiratory and/or cardiac arrest. Concurrent administration of buprenorphine can lead to respiratory arrest and circulatory collapse

	The concurrent use of benzodiazepines and sodium oxybate should be avoided due to the possibility of increasing risk of respiratory depression.
Adverse reactions	Common or very common - Appetite abnormal; concentration impaired; gastrointestinal disorder; movement disorders; muscle spasms; palpitations; sensory disorder; vomiting; drowsiness; numbed emotions; reduced alertness; confusion; amnesia; headaches; dizziness; dysarthria; tremor; anxiety; altered mood; vision disorder Uncommon - Constipation; diarrhoea; hypersalivation; speech slurred. Rare or very rare - Bradycardia; bronchial secretion increased; cardiac arrest; dry mouth; gynaecomastia; heart failure; leucopenia; loss of consciousness; memory loss; respiratory arrest; sexual dysfunction; syncope; urinary incontinence and retention; vertigo; hallucination; jaundice; restlessness; paradoxical drug reaction Frequency not known - Apnoea; nystagmus With rectal solution – Psychosis and skin reactions
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	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.
Patient advice / follow up treatment	Inform the individual/carer of possible side effects and their management. The individual/carer should be advised to seek medical advice in the event of an adverse reaction. Explain if/why transfer to hospital or GP is required and provide the details of medicine, time and dose to patient/carer/transport Patients treated with Diazepam must not drive for at least 24 hours after administration of the last dose.
Records	Record the following information on ePMA (Electronic Prescribing system) UHDB – Meditech

	Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following: • 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 administration • dose, form, and route of administration • quantity administered • batch number and expiry date (if applicable e.g., injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm administered and that this was done via Patient Group Direction (PGD) Records should be signed and dated (or a password-controlled e-records). All records should be clear, legible, and contemporaneous.

6. Key references

Key references	• Electronic Medicines Compendium https://www.medicines.org.uk/emc/product/2997/smpc accessed 17/09/24 • https://www.medicines.org.uk/emc/product/3001/smpc accessed 17/09/24 • Electronic BNF https://bnf.nice.org.uk/drugs/diazepam/ accessed 17/09/24 • Management of prolonged convulsive epileptic seizures in children and young people - Derby and Burton https://derby.koha-ptfs.co.uk/cgi-bin/koha/opac-retrieve-file.pl?id=bcea22cca13f1b13eedb33d7c0edc3e2 accessed 17/09/24 • Febrile seizure - NICE CKS https://cks.nice.org.uk/topics/febrile-seizure/ accessed 17/09/24 • Trust Policy: Chaperoning https://derby.koha-ptfs.co.uk/cgi-bin/koha/opac-retrieve-file.pl?id=8c44c3f3412388ce31badd10c8b45dfc accessed 17/09/24 • "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2

7. Registered health professional authorisation sheet

PGD Name [version]: QHB - ED/MIU - Diazepam Rectal [v2]
PGD ref: UHDB103

Valid from: 28/11/2024 Expiry date: 27/11/2027

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.