University Hospitals of Derby and Burton
NHS Foundation Trust

# PATIENT GROUP DIRECTION (PGD)

## Administration/Supply of DIAZEPAM ORAL TABLETS

## By Registered Nurses, Emergency Nurse Practitioners (ENP), Emergency Care Practitioners (ECP) and Emergency Physiotherapy Practitioners (EPP) In Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals

## Documentation details

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| Reference no: | UHDB207 |
| Version no: | 1 |
| Valid from: | 29/11/2022 |
| Review date: | 28/05/2025 |
| Expiry date: | 28/11/2025 |

## Change history

| Version number | Change details | Date |
|---|---|---|
| 1 | New UHDB format | 19/10/2022 |
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## Glossary

| Abbreviation | Definition |
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## 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 Thungala | Doctor |
| James Kerr | Pharmacist |
| Alannah Davies | Representative of RNMHP Group |
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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** |
|---|
| 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** |
| Nil |

| **Organisational Authorisation (legal requirement).** | | | |
|---|---|---|---|
| **Role** | **Name** | **Sign** | **Date** |
| Medicines Safety Officer & Deputy CD Accountable Officer<br><br>*Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)* | James Hooley | **Signed copy held by Pharmacy** | **29/11/2022** |

| Additional signatories (required as per legislation and locally agreed policy) | | | |
|---|---|---|---|
| **Role** | **Name** | **Sign** | **Date** |
| Divisional Pharmacist - Medicine<br><br>*Clinical Pharmacist from PGD working group* | **James Kerr** | **Signed copy held by Pharmacy** | **16/11/2022** |
| Consultant<br><br>*Doctor* | **Dr. Thungala** | **Signed copy held by Pharmacy** | **29/11/2022** |
| Senior Sister/ ENP<br><br>*Registered Professional representing users of the PGD* | **Alannah Davies** | **Signed copy held by Pharmacy** | **24/10/2022** |

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

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| **Qualifications and professional registration** | Registered professional with current professional registration operating within their usual scope of practice. Must be a profession permitted by current legislation to practice under a patient group direction. |
| **Initial training** | - Completion of all Essential-to-role training as outlined in the UHDB PGD policy.<br>- Individual has read and understood full content of this PGD and signed authorisation (section 7)<br>- Completion of Medicines Management Drug Assessment<br>- 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. |
| **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<br>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 senior individual responsible for authorising individuals to act under the PGD and further training provided as required. |
| **Ongoing training and competency** | - Annual Medicines Safety Training (essential to role)<br>- Review/repeat initial training above when this PGD is revised<br>- The registered healthcare practitioner will ensure Anaphylaxis/CPR training is kept updated yearly.<br>- The registered healthcare professional must actively take part in CPD and annual individual performance reviews.<br>-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

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| **Clinical condition or situation to which this PGD applies** | • Pain due to muscle spasm |
| **Criteria for inclusion** | • Adults presenting with severe muscle spasm |
| **Criteria for exclusion** | • Children (aged under 18 years)<br>• Pregnant<br>• Breastfeeding<br>• Hypersensitivity to any of the ingredients<br>• Patients currently taking opioids (see also 'Drug interactions')<br>• Pulmonary insufficiency, respiratory disease, sleep apnoea<br>• Severe hepatic impairment<br>• Chronic psychosis, phobic or obsessional state<br>• Myasthenia gravis<br>• Acute porphyria<br>• History of drug or alcohol dependence or abuse |
| **Cautions including any relevant action to be taken** | • Inform patient any degree of disorientation or confusion or signs of severe allergy should be seen in ED. |
| **Action to be taken if the patient is excluded** | • Patients with any exclusions, any degree of disorientated or confusion, over 65's or severe renal impairment should be seen by a Doctor (e.g. GP or A&E) |
| **Action to be taken if the patient or carer declines treatment** | • Discuss need for treatment<br>• Document advice given<br>• Advise patient on alternative treatment |
| **Arrangements for referral for medical advice** | • Physio input may be of use if available, if recurrent refer back to GP. |

## 5. Description of treatment

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| **Name, strength & formulation of drug** | Diazepam<br>Oral tablets<br>2mg tablets |
| **Legal category** | POM |
| **Route / method of administration** | **PO**<br>**Oral tablet** |
| **Indicate any off-label use (if relevant)** | *None* |
| **Dose and frequency of administration** | **Adult**<br><br>**4mg as STAT dose**<br><br>BNF Indications and doses Diazepam oral tablet<br><https://bnf.nice.org.uk/drugs/diazepam/#indications-and-dose.> |

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| **Duration of treatment** | A further 4mg up to THREE times a day may be taken if required<br><br>Max 12mg in a day |
| **Quantity to be supplied (leave blank if PGD is administration ONLY)** | ONE TTO pack of 6 x 2mg tablets may be supplied<br><br>Each pack must be appropriately labelled with:<br><br>• Patient's name<br>• Date of supply<br>• Clear dosage instructions indicating take 2 tablets up to three times a day if required<br>• Name and address of supplying MIU/ED department<br><br>All packs issued must contain the manufacturer's information leaflet |
| **Storage** | Store below 25°C and protect from light.<br>Do not refrigerate or freeze.<br>The storage at temperatures higher than 25°C could lead to precipitation inside the solution. Do not use the product if solid particles are observed inside the solution.<br><br>Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below:<br><br>Available from the electronic Medicines Compendium website available at: <https://www.medicines.org.uk/emc/product/4523> Accessed 15/05/22 |
| **Drug interactions** | • **Avoid concomitant use with:**<br>- Clozapine<br>- Azoles (fluconazole, itraconazole, ketoconazole, voriconazole)<br>- Fluoxamine<br>- HIV anti-virals (e.g. Ritonvir, atazanavir, delavirdine, efavirenz, indinavir, nelfinavir, saquinavir)<br>- Sodium Oxybate<br>- Voriconazole<br>- Anti-epileptic drugs<br>- Narcotic analgesics<br><br>**<u>Possible increased adverse effects with:</u>**<br>- Alcohol<br>- Anti-hypertensives<br>- Drugs that affect liver enzyme pathways (e.g. Isonazid, omeprazole, erythromycin, itraconazole)<br>- Opoid analgesics<br>- Phenobarbitone<br>- Other muscle relaxants (e.g. Tizanidine, Baclofen)<br>- Any medicines that may have a CNS depressant effect and cause sedation or may affect ability to perform skilled tasks such as driving.<br>- Caffeine<br>- Grapefruit juice<br>- Antacids |

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| | - Anti-hypertensives, vasodilators& diuretics<br>- Isoniazid<br>- Itraconazole<br>- Fluoexeteine<br>- Disulfiram<br>- Cisapride<br>- Ketamine<br><br>• Oral contraceptive pill; may cause breakthrough bleeding with diazepam<br>• Carbamazepine, corticosteroids, omeprazole, esomeprazole, increases hepatic metabolism of diazepam therefore reducing effect of diazepam<br>• Diazepam may reduce effect of Levodopa<br>• Phenytoin: levels can be affected in an unpredictable way by diazepam (increased/decreased/unaltered). Less likely at low doses advised in above PGD and short duration. However advise patient to be vigilant for phenytoin related side effects (increased levels) or concerns in relation to seizure control. Seek medical advice if concerned, may need phenytoin levels checking. |
| **Adverse reactions** | Common or very common<br>• Appetite abnormal; concentration impaired; gastrointestinal disorder; movement disorders; muscle spasms; palpitations; sensory disorder; vomiting<br><br>Uncommon<br>• Constipation; diarrhoea; hypersalivation; speech slurred; skin reactions<br><br>Rare or very rare<br>• Bradycardia; bronchial secretion increased; cardiac arrest; dry mouth; gynaecomastia; heart failure; leucopenia; loss of consciousness; memory loss; respiratory arrest; sexual dysfunction; syncope; urinary incontinence; vertigo; Psychiatric disorder; psychosis<br><br>Frequency not known<br>• Apnoea; nystagmus; |
| **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<br>• Record all adverse drug reactions (ADRs) in the patient's medical record.<br>• 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. |

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| | • If Anaphylaxis occurs treat as per local emergency protocols and transfer to A&E via 999 if appropriate to area. |
| **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** | • Explain importance of using treatment only if symptoms are present<br>• Advise on the likelihood of adverse effects that may impact on ability to drive or operate machinery.<br>• Explain alcohol will potentiate the effect<br>• The medicine is included in the Road Traffic Act 1988 section 5a, it is an offence to drive whilst taking this medication unless:<br>- You are taking for a medical condition<br>- You are taking it according to the instructions<br>- You do not drive until you know how the medicine will affect you<br>- You do not have any affects that could impact on your ability to drive safely<br><br>Advised patient NOT to drive if the drug affects their ability to drive safely.<br>Patients can find further information at: < https://www.gov.uk/drug-driving-law> |
| **Records** | Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following:<br>• name of individual, address, date of birth and GP with whom the individual is registered (if relevant)<br>• name of registered health professional<br>• name of medication supplied/administered<br>• date of supply/administration<br>• dose, form and route of supply/administration<br>• quantity supplied/administered<br>• batch number and expiry date (if applicable e.g. injections and implants)<br>• advice given, including advice given if excluded or declines treatment<br>• details of any adverse drug reactions and actions taken<br>• Confirm whether supplied and/or administered and that this was done via Patient Group Direction (PGD)<br>Records should be signed and dated (or a password controlled e-records).<br>All records should be clear, legible and contemporaneous.<br><br>If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy. |

## 6. Key references

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| **Key references** | • Electronic Medicines Compendium: Available at: <https://www.medicines.org.uk/emc/product/4523> Accessed 15/5/22<br>• Electronic BNF, Available at: <https://bnf.nice.org.uk/drugs/diazepam/#> Accessed 15/5/22<br>• Government Drug, Driving law, Available at < https://www.gov.uk/drug-driving-law> Accessed 15/5/22<br>• Patient Group Direction Diazepam Oral Tablets, UHDB. Available at: < https://derby.koha-ptfs.co.uk/cgi-bin/koha/opac-retrieve-file.pl?id=7b82bd3347f8a46856d6385331f92258> Accessed 15/5/22<br>• NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2<br>• https://medusa.wales.nhs.uk |

## 7. Registered health professional authorisation sheet

**PGD Name [version]: ED/MIU/Ambulatory Care – Diazepam Oral [v1]**
**PGD ref: UHDB207**

**Valid from: 29/11/2022 Expiry date: 28/11/2025**

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.** | | | |
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| **Name** | **Designation** | **Signature** | **Date** |
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### 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** |
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**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.