University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of Glyceryl trinitrate 400microgram spray By Registered UHDB Staff in Adult UHDB services

Documentation details

Reference no:	UHDB029
Version no:	1.0
Valid from:	16/09/2021
Review date:	16/03/2024
Expiry date:	15/09/2024

Change history

Version number	Change details	Date
1	New template – Extended for all UHDB staff on any site	

Glossary

Abbreviation	Definition

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
James Hooley	Medicines Safety Officer (Pharmacist)
Core Adult PGD list maintained by Medicines Safety Group.	Note: No PGD working group convened as this PGD is created by merging detail from multiple authorised PGDs in active use across UHDB which have been developed previously with nursing and medical input.

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	-	-

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
All UHDB staff providing UHDB services (includes UHDB staff/services undertaken on non-UHDB premises) This is a core PGD and <u>can</u> be implemented in all adult services where training and resources have been allocated by senior staff to do so (see policy and limitations below if in doubt).
Limitations to authorisation
It is the responsibility of the practitioner working under this PGD to ensure that this PGD is in place in the area they are practising at the time of use. In most cases, this is implicit when a senior manager requests the staff to undertake training and then authorises them in section 7 of this document. However, when working in alternative areas (e.g. internal bank or redeployment) it is important that the practitioner confirms with a departmental manager in the new department that the core PGDs are in-use in their area.

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Chief Pharmacist	**Clive Newman**	Signed copy held in Pharmacy	**23/08/2021**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer (pharmacist) *Clinical Pharmacist from PGD working group*	**James Hooley**	Signed copy held in Pharmacy	**18/08/2021**
Medical Director or Deputy *Doctor*	**Magnus Harrison**	Signed copy held in Pharmacy	**18/08/2021**
Chief Nurse or Deputy *Registered Professional representing users of the PGD*	**Catherine Winfield**	Signed copy held in Pharmacy	**11/08/2021**

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	All Divisions, Adult Areas, 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. - Individual has read and understood full content of this PGD and signed authorisation (section 7) - Completion of Medicines Management Drug Assessment
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 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.
Ongoing training and competency	Annual Medicines Safety Training (essential to role) Review/repeat initial training above when this PGD is revised
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	To relieve angina pain or suspected ischaemic chest pain whilst awaiting or referring urgent review by a doctor
Criteria for inclusion	• Known or suspected angina; • Patients over 16 years presenting with symptoms of the above (including tightness across the chest radiating into the back/neck/jaw and/or heaviness in the inner aspect of the arms) • Pregnancy/breast-feeding patients can be considered following cautions below
Criteria for exclusion	• Under 16 years • Previous sensitivity or intolerance to the drug (or other nitrates) or any ingredient; • Acute circulatory failure (shock, collapse). • Hypotension with systolic <90mmHg • Hypovolaemia; • aortic &/or mitral stenosis, • cardiac tamponade; • constrictive pericarditis; • hypertrophic cardiomyopathy; • Toxic pulmonary oedema or Primary pulmonary hypertension; • known severe anaemia; • recent (last 24 hours) use of Sildenafil, Tadalafil and Vardenafil; • known closed-angle glaucoma; • known severe renal or hepatic impairment; • raised intracranial pressure due to cerebral haemorrhage or cerebral/head trauma;
Cautions including any relevant action to be taken	• Pregnancy – Not known to be harmful but consider risk:benefit prior to administration • Breast-feeding – Limited information – manufacturer advises avoid unless potential benefit outweighs risk. However, discuss with lady as it may be appropriate to suspend breast-feeding or expressing milk for a period after GTN use e.g. if formula or previously expressed milk is available for the infant; • Tolerance to this drug and cross-tolerance to other nitrates may occur (see BNF for more information); • should be used with caution in patients with cerebrovascular disease since symptoms may be precipitated by hypotension. • Hypoxaemia - may worsen hypoxaemia in patients with lung disease or cor pulmonale. • Special caution and close medical control is required in patients predisposed to postural hypotension. • This medicine should be administered carefully to patients with narrow angle glaucoma, or migraine. • Manufacturer advises caution in: hypothyroidism; malnutrition; hypothermia; recent myocaridal infarction; • Alcohol should be avoided because of the hypotensive effect. • PLEASE NOTE: This medicine contains ethanol (alcohol). Its use

	may affect patient with liver disease, alcoholism, epilepsy, cerebral trauma and other CNS diseases, pregnancy and childhood. • This medicine contains propylene glycol and may cause skin irritation
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 or medical staff for review and prescribing of alternative agent
Action to be taken if the patient or carer declines treatment	• Document advice given • Advise patient on alternative treatment • Refer to a prescriber or medical staff
Arrangements for referral for medical advice	Contact your ward or clinic medical team or prescriber in the first instance except in the event of anaphylaxis/cardiac arrest when you should follow your local medical emergency procedures (e.g. 2222 / 3333 / 999 procedures)

5. Description of treatment

Name, strength & formulation of drug	Glyceryl Trinitrate 400 micrograms/metered dose, sublingual spray
Legal category	Pharmacy only (P)
Route / method of administration	Spray sublingually (under tongue) and immediately close mouth.
Indicate any off-label use (if relevant)	n/a
Dose and frequency of administration	• 1 to 2 sprays (400-800 micrograms) to be administered under tongue and then close mouth • Dose may be repeated at 5 minute intervals if required • if symptoms have not resolved after 3 doses, medical attention should be sought if not already done so. • There is no need to shake the canister before dosing • The canister should be held vertically with the spray head uppermost • The pump may need to be primed when first used or if the product has not been used for a period of time. The priming actuation should be released into the air. **Ensure patient is sitting down before treatment is administered**
Duration of treatment	*For immediate treatment only, maximum 3 doses.*
Quantity to be supplied (leave blank if PGD is administration ONLY)	n/a under PGD but supplies may later be made against a prescription following review by a prescriber.

Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: Do not store above 25°C. Do not refrigerate or freeze. Glyceryl Trinitrate Spray is an aerosol spray and contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not pierce the aluminium container (canister), even when empty. It should not be sprayed at a naked flame or any incandescent material. Patients, especially those who smoke should be warned not to use Glyceryl Trinitrate Spray near a naked flame.
Drug interactions	The following interactions have been identified and should be considered where it is known a patient is on the following medicines: **Phosphodiesterase type 5 inhibitors (e.g. sildenafil, vardenafil and tadalafil)** have been shown to potentiate the hypotensive effects of nitrates - **See Exclusions: Never co-administer within 24 hours** • Treatment with other agents with hypotensive effects (Vasodilators, antihypertensives, ß-blockers, calcium antagonists, neuroleptics, tricyclic antidepressants and diuretics) can increase nitrate induced hypotension. • Alcohol can increase side effects • N-acetylcysteine may potentiate the vasodilator effects of glyceryl trinitrate • There is evidence that systemic nitrates may interfere with the anticoagulant effects of heparin A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions	Common or very common Arrhythmias; asthenia; cerebral ischaemia; dizziness; drowsiness; flushing; headache; hypotension; nausea; vomiting Uncommon Circulatory collapse; diarrhoea; skin reactions; syncope; cyanosis; tongue blistering Rare or very Rarely: methaemoglobinaemia; respiratory disorder; restlessness A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
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. Headache from GTN can be helped by a single dose of Paracetamol if necessary.
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	Spray must go underneath the patient's tongue and the patient instructed to close mouth following administration. Inform patient that drug onset should occur within 2 minutes of administration and its effects last about 30 minutes. If they have no relief after 15 minutes, report to nurse. May cause throbbing headache, flushing, dizziness, metallic taste, postural hypotension, tachycardia. These are usually transient in nature and resolve quickly but should be reported to nursing staff promptly.
Records	For inpatients, the record of administration must be documented in the ePMA system or medicines chart used in your area. For other areas, an ePMA system should be used if in-use in your area as this will ensure all legal criteria are fulfilled and auditable. Otherwise, records can be made in the medical notes or within the patient pathway (e.g. in daycase or triage where a pathway booklet is in use) but must include the legal requirements below. 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 supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/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 whether supplied and/or administered 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. 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

Key references	• *Electronic Medicines Compendium http://www.medicines.org.uk/* Accessed 11/05/2021 • *Electronic BNF https://bnf.nice.org.uk/ Accessed11/05/2021*

7. Registered health professional authorisation sheet

PGD Name [version]: Glyceryl trinitrate 400microgram spray [v1.0] PGD ref: UHDB029
Valid from: 16/09/2021 Expiry date: 15/09/2024

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.