Tees, Esk and Wear Valleys
NHS Foundation Trust

Patient Group Direction for the supply and/or administration of:

Zopiclone 7.5 mg tablets

To:

Adult patients referred to a crisis team

PGD 10

Status: Approved

This Patient Group Direction has been endorsed for use by:

Title	Name	Signature	Date
Medical Director	Dr Stephen Wright	*	21/2/2022
Director of Nursing and Governance	Elizabeth Moody	*	04/03/2022
Chief Pharmacist	Chris Williams	*	21/2/2022

This Patient Group Direction has been approved by:

Title	Name	Signature	Date
Drug and Therapeutics Committee	Dr Baxi Sinha (Chair)	*	28/2/2022

* signed copy available on request for audit purposes

Contents

1. Clinical condition or situation to which the Patient Group Direction applies

Define situation/condition	Short term treatment of insomnia in adults.
Objectives of care	To alleviate distress from insomnia without the need to wait for the attending medical officer or for unnecessary admission to hospital.
Patient criteria for inclusion	Aged over 18 years presenting to a crisis team with the situation/condition above for which non-pharmacological options have failed or are considered unsuitable.

Patient criteria for exclusion
NB. Exclusion from supplying/administering zopiclone under a PGD may not necessarily exclude supply/administration following the direction of a prescriber.
	• Under 18 years of age.
	• Over 65 years of age and not previously taken zopiclone (recommended dose of 3.75 mg not covered by this PGD)
	• On a Community Treatment Order (CTO)
	• Intoxication with alcohol
	• Known sensitivity or intolerance to zopiclone.
	• Already taking prescribed hypnotic medication.
	• History of withdrawal from treatment with either benzodiazepine or non-benzodiazepine hypnotics
	• Previous dependency on zopiclone.
	• Confirmed, suspected or intended pregnancy
	• Breast feeding
	• Any of the following contra-indications or conditions requiring dose adjustment (see SPC for details)
	  ➢ Myasthenia gravis
	  ➢ Respiratory failure
	  ➢ Severe sleep apnoea syndrome
	  ➢ Hepatic insufficiency
	  ➢ Renal insufficiency
	  ➢ Hypersensitivity to zopiclone or to any of the excipients
	• Suspected likelihood of abuse or diversion (as with all hypnotic drugs zopiclone has the potential to be abused. Caution should be exercised in ensuring it is only supplied under this direction to patients exhibiting genuine symptoms)

Action if excluded	• Explain reason for exclusion to the patient • If on CTO, or other MHA restriction, liaise with on-call consultant (a Section 62 emergency treatment form **must** be completed if treatment required). • Seek further medical advice. • Document in patient record.
Action if patient declines treatment	• Seek further medical advice • Document in patient record.
Reference to national/local policies or guidelines	• Summary of product characteristics (Zimovane ®) • British National Formulary • NICE Technology Appraisal 77 – Guidance on the use of zaleplon, zolpidem and zopiclone for the short-term management of insomnia. • RCN Medicines Management. • NICE MPG2 – Patient Group Directions • TEWV Medicines Overarching Framework • TEWV PGD Overarching Framework

2. Characteristics of staff

Qualifications required	• Registered Nurse with current NMC registration.
Additional experience / training required	• Permanent employee of the Trust and has completed preceptorship training. • Current member of a Trust crisis team or equivalent • Has undertaken appropriate training to carry out clinical assessment of patients leading to diagnosis that requires treatment according to the indications listed in the PGD. • Has undertaken appropriate training for working under patient group directions for the supply and administration of medicines and registered to use this PGD.
Continued training requirement	• **Must** be approved to supply zopiclone using the PGD. • **Must** complete PGD training review every 3 years. • Nurses **must** keep up to date regarding amendments in the use of zopiclone and Trust prescribing policies.

3. Description of treatment

Name, strength & formulation of drug	Zopiclone 7.5 mg tablets
Legal class	POM Controlled Drug (CD) Schedule 4, part 1
Dose/dose range	7.5 mg
Method/route	Oral
Frequency of administration	Once per night-time period
Maximum dose & number of treatments	7.5 mg per night time period Normal supply - for single night time period (1 tablet only); supply may be repeated up to three times (maximum of four night time periods) to cover weekends & Bank Holidays if necessary.
Presentation of medicines for supply	1 x 7.5 mg tablet.
Follow-up treatment	Seek medical advice if no improvement in symptoms after 24 hours.

3.1. Further aspects of treatment

Patient advice (verbal and written)	• Ensure patient is aware of maximum daily dosage. • Avoid other sedatives, e.g. opioid analgesics, including over the counter medications. • Drowsiness may persist until the next day. • Do **not** drink alcohol whilst taking zopiclone. • Advise **not** to drive or operate machinery • Possible side effects – metallic aftertaste (common), nausea, vomiting, dry mouth, dizziness, headache, light-headedness, lack of co-ordination, urticaria, rashes, hallucinations, nightmares, amnesia. • Give patient a copy of the patient information leaflet from the Choice & Medication website
Identification & management of adverse reaction(s)	• Request patient to report any adverse effects.

Reporting procedure of adverse reaction(s)	• Report to appropriate case manager. • Document in patient record. • Yellow card to MHRA for severe or unusual reactions.
Arrangements for referral to medical advice	• Consult appropriate medical practitioner (GP/SHO/consultant).
Additional facilities / supplies required	• Secured in a locked medicine cabinet at room temperature (storage temperatures should not exceed 25ºC).
Records	• An entry to be made on the PGD record sheet (Appendix 1). • An entry to be made in the electronic patient record.

4. Management and authorisation of Patient Group Direction

I have read and understood this Patient Group Direction and agree to supply this medicine only in accordance with this PGD.

- PGDs do not remove inherent professional obligations or accountability
- PGDs should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. Summary of Product Characteristics) and do NOT replace the need to refer to such sources
- It is the responsibility of each professional to practice only within the bounds of their own competence

Note to authorising managers: **All nurses authorised to use this PGD must have received training as defined within the PGD and be competent to supply/administer the medicines identified in the PGD.** Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the authorisation sheet showing their authorisation.

Pre-requisition – successful completion of PGD theory e-learning package (100%)		
Successful completion evidenced via ESR: Y / N	Date	Checked and confirmed by: Signature:
PGD specific associated pre-requisitions		
Subject: Successful completion evidenced by proof of course attendance: Y / N	Date	Checked and confirmed by: Signature:
Subject: Successful completion evidenced by proof of course attendance: Y / N	Date	Checked and confirmed by: Signature:
For the administration and/or supply of: Zopiclone to patients under the care of the crisis resolution team.		
Name of Nurse		
Authorising Trainer		
Successful completion evidenced by proof of course attendance: Y / N	Date	Checked and confirmed by: Signature:
The above named nurse is authorised to work within the confines of this PGD		
Authorising Manager & Designation:	Signature:	
I, the undersigned, have read and understood this PGD. I have attended a specific information and training session/completed the appropriate e-learning package for the implementation of this PGD and can safely implement this PGD		
Signature of named nurse	Date	Review date
Record Keeping		
One copy with PGD to be retained by named nurse; one copy to personal file		

Appendix 1

PGD 10 – Recording sheet for zopiclone 7.5 mg tablets

UNIT/WARD/TEAM	LOCATION	SHEET NO

DATE	PATIENT'S NAME	DOB and/or NHS No.	QUANTITY	DOSE	TIME	GIVEN/SUPPLIED BY	RUNNING TOTAL	REQUISITION NUMBER
	Starting balance (transferred from previous sheet)							