Zopiclone 7.5mg tablet

GG&C PGD ref no: 2023/2485

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

Change history

Date	Version number	Update
15/02/2023	2	Inclusion & exclusion criteria changed from 16+ years to 18+ years
	3	No changes

Clinical Condition	
Indication:	Immediate treatment of insomnia, including difficulties in falling asleep, nocturnal awakening and early awakening – secondary to psychiatric disturbances when the patient's insomnia is debilitating or causing severe distress for the patient, and this cannot be relieved by any other intervention.
Inclusion criteria:	Patients aged 18 and over referred to the GGC Community Mental Health Acute Care Service (CMHACS) or the Mental Health Assessment Units for immediate treatment of insomnia when this cannot be relieved by any other intervention. Presenting symptoms include • Difficulty in falling asleep • Nocturnal awakening • Early wakening
Exclusion criteria:	• Patients under 18 years of age • Patients who have consumed alcohol within the past 24 hours • Patient is already in receipt of regular hypnotic medication • Known hypersensitivity to zopiclone or any excipients • Unstable myasthenia gravis • Respiratory failure • Severe sleep apnoea syndrome • Known severe hepatic insufficiency • Known renal insufficiency • Known pregnancy • Known breastfeeding • Current substance abuse • Patients with rare hereditary problems of galactose intolerance, the lactase deficiency or glucose-galactose malabsorption should not take this medicine (see PIL) • Patients taking CNS depressants or sedatives
Cautions/Need for further advice/Circumstances when further advice should be sought from the prescriber:	• Over 65 years of age • History of substance abuse • Compounds which inhibit cytochrome P450 may enhance effect of zopiclone (e.g. Erythromycin) • Compounds which induce CPY3A4 can decrease levels of zopiclone when co-administered (e.g. carbamazepine, Phenytoin, St John's Wort)

	See Summary of Product Characteristics (SPC) for interactions with other medicinal products
Action if patient declines or is excluded:	• Document on the patient's EMIS Mental Health record • Discuss with patient the reasons for exclusion • Refer to prescriber for review if appropriate
Referral arrangements for further advice / cautions:	• Refer to prescriber for review if appropriate

Zopiclone 7.5mg tablet

Drug Details	
Name, form & strength of medicine:	Zopiclone 7.5mg tablet
Route/Method of administration:	Oral
Dosage (include maximum dose if appropriate):	7.5mg as a single treatment dose at night for adults
Frequency:	Once daily at night
Duration of treatment:	Up to 2 nights
Maximum or minimum treatment period:	2 nights
Quantity to supply/administer:	2 tablets
Supply, Administer or Both:	Supply only
▼Additional Monitoring:*	No
Legal Category:	POM
Is the use outwith the SPC:**	No
Storage requirements:	Store below 25^{o}C

*** The black triangle symbol has now been replaced by European "additional monitoring" (▼)**

**** Summary of Product Characteristics**

Zopiclone 7.5mg tablet

Warnings including possible adverse reactions and management of these:	Common adverse effects include • Metallic taste • Nausea and vomiting • Day time drowsiness • Headache • Confusion • Dizziness Please refer to current BNF or SPC for full details Use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on its use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/
Advice to patient/carer including written information provided:	Explain treatment and course of action. Give patient a copy of relevant patient information leaflet, if appropriate. https://www.choiceandmedication.org/nhs24/ Patients should be told to contact appropriate healthcare professional or their GP should they experience a suspected adverse drug reaction. If condition worsens or symptoms persist then seek further medical advice
Monitoring (if applicable):	n/a
Follow up:	Inform GP of treatment Refer for medical review if appropriate

Zopiclone 7.5mg tablet

Staff Characteristics	
Professional qualifications:	Those registered health care professionals that are listed and approved in legislation as able to operate under patient group directions and have current registration.
Specialist competencies or qualifications:	Has undertaken appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD. Has undertaken appropriate training for working under PGDs for the supply and administration of medicines.
Continuing education & training:	Maintains current knowledge of the clinical use of zopiclone including side-effects, contra-indications, cautions, doses and interactions. The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development. Up to date BLS training & or MET

Referral Arrangements and Audit Trail	
Referral arrangements	Patient is discussed and reviewed by CMHACS or MHAU staff or appropriate medical staff if applicable
Records/audit trail:	Patient's name, address, date of birth and consent given; Contact details of GP (if registered); Diagnosis; Dose, form administered and batch details; Advice given to patient (including side effects); Signature/name of staff who administered or supplied the medication, and also, if relevant, signature/name of staff who removed/discontinued the treatment; Details of any adverse drug reaction and actions taken including documentation in the patient's medical record; Referral arrangements (including self-care)

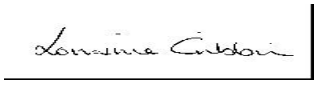
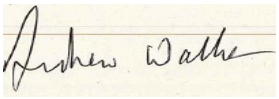
References/Resources and comments:	Notes: SPC – Summary of Product Characteristics https://www.medicines.org.uk/emc/ BNF – British National Formulary https://bnf.nice.org.uk/ Locally agreed Protocol

Zopiclone 7.5mg tablet

This Patient Group Direction must be agreed to and signed by all healthcare professionals involved in its use. The original signed copy will be held at Pharmacy Services, Clarkston Court, 56 Busby Road, Glasgow. The PGD must be easily accessible in the clinical setting.

Organisation:	**NHS Greater Glasgow & Clyde**

Professionals drawing up PGD/Authors

	Designation and Contact Details
*Name: Dr Una Graham  Signature: Date:	Designation: Deputy Associate Medical Director E-mail address: Una.Graham@nhs.scot
Name: Lorraine Cribbin Signature:  Date:	Designation: Interim Chief Nurse Adult Services E-mail address: Lorraine.cribbin@nhs.scot
Name: Andrew Walker Signature:  Date:	Designation: Lead Clinical Pharmacist E-mail address: Andrew.walker11@nhs.scot
Name: Signature: Date:	Designation: E-mail address:
Name: Signature: Date:	Designation: E-mail address:

*** Lead Author**
**** Antimicrobial Pharmacist if appropriate**

AUTHORISATION:

NHSGG&C PGD Sub-Committee of ADTC		
Chairman in BLOCK CAPITALS	**Signature:**	**Date:**
Dr Craig Harrow		

NHSGG&C PGD Sub-Committee of ADTC		
Lead Nurse, North Sector, NHS GG&C in BLOCK CAPITALS	**Signature:**	**Date:**

Pharmacist representative of PGD Sub-Committee of ADTC		
Name: in BLOCK CAPITALS	**Signature:**	**Date:**
Elaine Paton		

Antimicrobial use **If the PGD relates to an antimicrobial agent, the use must be supported by the NHS GG&C Antimicrobial Management Team (AMT). A member of this team must sign the PGD on behalf of the AMT.**		
Microbiology approval	Name:	Designation:
	Signature: (on behalf of NHS GG&C AMT)	Date:

Zopiclone 7.5mg tablet

Local Authorisation:

Service Area for which PGD is applicable:			
I authorise the supply/administer medicines in accordance with this PGD to patients cared for in this service area.			
Lead Clinician for the service area (Doctor)			
Name:	**Signature:**	**Designation:**	**Date:**
E-Mail contact address:			

I agree that only fully competent, qualified and trained professionals are authorised to operate under the PGD. Records of nominated individuals will be kept for audit purposes.			
Name (Lead Professional)**:**	**Signature:**	**Designation:**	**Date:**
E-Mail contact address:			

Description of Audit arrangements:			
Frequency of checks: (Generally annually)		**Names of auditor(s):**	

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction. I acknowledge that it is a legal document and agree to supply/administer this medicine only in accordance with this PGD.

Name of Professional	**Signature**	**Date**

Zopiclone 7.5mg tablet

Patient Group Direction Audit Form
Form for the audit of compliance with PGD or PGDs

To ensure best practice all PGDs should be audited on a 6 monthly basis.

Name and post of Designated Lead person within each practice/clinic base:			
Location/Clinic Base: **Date of audit:**			
Tick as appropriate. If 'no', state action required	**Y**	**N**	**Action**
Is the PGD or PGDs utilised within the clinical area?			
Has the PGD or PGDs been reviewed within the 2 year limit?			
Do the managers listed on the PGD or PGDs hold a current list of authorised staff?			
Are all staff authorised to work under the PGD or PGDs members of one of the health professions listed in the PGD?			
Do all staff meet the training requirements identified within the PGD?			
Are you confident that all medicines supplied or administered under the PGD or PGDs are stored according to the PGD where this is specified?			
Do the staff working under the PGD or PGDs have a copy of the PGD which has governance sign off and is in date and, available for reference at the time of consultation?			
Where the medicine requires refrigeration. (Delete if not required).			
Is there a designated person responsible for ensuring that the cold chain is maintained?			
Is there a record that the fridge temperature has been monitored to required levels?			
If there is regular and sustained reliance on PGDs for service provision has a Non Medical Prescribing approach been considered as an alternative? (Please note reasons for either a Y/N response).			

Name:	Date of audit:

Keep copies of completed audits alongside your PGD for local reference.
Please retain at local level and ensure audit forms are readily available as they may be required for clinical governance audit purposes.