East London NHS Foundation Trust

Zopiclone 7.5mg tablets

Patient Group Direction (PGD) for the supply/administration of 4 x Zopiclone 3.75mg tablets

By a registered nurse with current Nursing and Midwifery Council (NMC) registration, working at East London NHS Foundation Trust who is assessed and deemed competent and thus authorised to work under this PGD. Access to the current edition of the British National Formulary and the Summary of Product characteristics and any relevant updates required.

>> YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION <<

>> OF THIS PGD BEFORE WORKING UNDER IT <<

to **Adults aged 18-65 years**

1. Clinical Condition

Define situation/condition	Insomnia (short term use)
Criteria for inclusion	• Adults aged between 18 – 65 years of age • Presenting with insomnia and unable sleep using non drug methods or sleep hygiene techniques, who may have already tried Promethazine or are unable to take it. • Patients are clients of ELFT Crisis and Home Treatment Teams, inpatient use

Criteria for exclusion (including contra-indications)	• Patients under 18 years of age or over 65 years of age. • Patients over the age of 65 years under the care of Mental Health Care of Older People. • People with dementia or delirium (acute confusional state) • Patients unable to give consent • Any underlying cause of the insomnia should also be addressed before symptomatic treatment e.g. depression • Pregnancy • Breastfeeding • Known hypersensitivity to zopiclone or tablet excipients • Respiratory depression • Respiratory failure • Any neuromuscular respiratory weakness • Respiratory disease as reported by the patient or documented in the notes or GP summary • Marked personality disorder • History of drug or alcohol abuse/dependence • Recent alcohol intake by assessment of the nurse • Severe anxiety or longstanding anxiety disorder • Debilitated patients • Liver or renal disease as reported by the patient or documented in the notes • Myasthenia Gravis (severe muscle weakness after exercise particularly in facial muscles which affects chewing, talking or swallowing) as reported by the patient or documented in the notes. • Severe sleep apnoea syndrome • Severe hepatic insufficiency • Who have previously experienced complex sleep behaviours after taking zopiclone • Patients already prescribed a hypnotic • Responsive to non-pharmacological intervention • Interactions with regular medication
Action if excluded	Contact duty doctor for review Document action taken in patient's records.
Action if patient declines	Advise patient of alternative sources of treatment. Consider treatment using alternative PGD if available eg promethazine Document refusal and action taken in patient's records. Refer to prescriber
Refer to doctor	If any exclusions or any drug interactions If recent bereavement

2. Description of treatment

Name of Medicine	Zopiclone 7.5mg tablets
POM/P/GSL	CD schedule 4
Dose(s)	<u>Adults</u> The recommended dose for adults is 7.5 mg (two tablets of 3.75 mg or one tablet of 7.5 mg) by the oral route shortly before retiring.
Route Method	oral
Frequency	At night (shortly before retiring to bed)

Supply	Maximum 4 x 3.75mg tablets
Mode of action	Enhances the body's natural GABA receptors which dampens the electrical activity in the brain
Pharmacokinetics	Peak concentrations reached within 1.5-2 hours. Elimination half-life (time taken for the concentration of Zopiclone to drop by half in the body) is approximately 5 hours.
Warnings and cautions	• Risk of dependence: Clinical experience to date with zopiclone suggests that the risk of dependence is minimal when the duration of treatment is limited to not more than 4 weeks. • The risk of dependence increases with dose and duration of treatment; it is also greater in patients with a history of alcohol and/or drug abuse, or those who have marked personality disorders. Refer to the doctor for any dependence to alcohol or drugs. • Tolerance: Some loss of efficacy to the hypnotic effect of benzodiazepines and benzodiazepine-like agents may develop after repeated use for a few weeks. However, with zopiclone, there is an absence of any marked tolerance during treatment periods of up to 4 weeks. • Rebound insomnia is a transient syndrome where the symptoms which led to treatment with a benzodiazepine or benzodiazepine-like agent recur in an enhanced form on discontinuation of therapy. It may be accompanied by other reactions including mood changes, anxiety and restlessness. Since the risk of withdrawal/rebound phenomena may be increased after prolonged treatment, or abrupt discontinuation of therapy, decreasing the dosage in a stepwise fashion may be helpful. • A course of treatment should employ the lowest effective dose for the minimum length of time necessary for effective treatment. • Amnesia is rare, but anterograde amnesia may occur, especially when sleep is interrupted or when retiring to bed is delayed after taking the tablet. Therefore, patients should ensure that they take the tablet when certain of retiring for the night and they are able to have a full night's sleep. • Reduced dose is necessary in the following patient groups: hepatic insufficiency, respiratory insufficiency, elderly patients • Withdrawal - termination of treatment with Zopiclone is unlikely to be associated with withdrawal effects when duration of treatment is limited to 4 weeks. Patients may benefit from tapering of the dose before discontinuation. • Some epidemiological studies show an increased incidence of suicidal ideation, suicide attempt and suicide in patients with or without depression, and treated with benzodiazepines and other hypnotics, including zopiclone. However, a causal relationship has not been established. • As with other hypnotics, zopiclone does not constitute a treatment for depression and may even mask its symptoms (suicide may be precipitated in such patients). • The risk of psychomotor impairment, including impaired driving ability, is increased if: zopiclone is taken within 12 hours of performing activities that require mental alertness, a dose higher than the recommended dose is taken, or zopiclone is co-administered with other CNS depressants, alcohol or with other drugs that increase the blood levels of zopiclone • Concomitant use of opioids with benzodiazepines or other sedative-hypnotic drugs, including zopiclone may result in sedation, respiratory depression, coma, and death. Because of these risks, reserve concomitant prescribing of opioids and benzodiazepines for use in patients for whom alternative treatment options are inadequate.

	• Other psychiatric and paradoxical reactions have been reported (see section 4.8), like restlessness, agitation, irritability, aggression, delusion, anger, nightmares, hallucinations, inappropriate behaviour and other adverse behavioural effects are known to occur when using sedative/hypnotic agents like zopiclone. Should this occur, use of zopiclone should be discontinued. These reactions are more likely to occur in the elderly. • Complex sleep behaviour, including sleep walking and other associated behaviours such as "sleep driving", preparing and eating food, making phone calls or having sex, with amnesia for the event, have been reported in patients who had taken zopiclone and were not fully awake. These events may occur following the first or any subsequent use of zopiclone. Discontinue treatment immediately if a patient experiences a complex sleep behaviour, due to the risk to the patient and others • Zopiclone tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. • This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.
Interactions	• Not to be used alongside alcohol, other hypnotics or anxiolytics, antiepileptic medication, sedative antihistamines, benzodiazepines, or narcotic analgesics. • Can interact with antipsychotics and antidepressants • Erythromycin, Clarithromycin, Ketoconazole, Itraconazole, Fluconazole, Tacrolimus and Ritonavir – can increase zopiclone levels • Rifampicin, carbamazepine, phenobarbital, phenytoin, St John's Wort can all reduce zopiclone levels • Metoclopramide • Opioids and concomitant use of benzodiazepines can increase the risk of sedation, respiratory depression, coma and death due to the additive CNS depressant effects.
Advice to patients	• Take dose about half an hour before going to sleep • Do not take another tablet if you wake up later • Advise caution when waking up the next day as may experience hangover effects, try to get 8 hours sleep • May cause a mild bitter or metallic after taste • Less common side effects might be, mild gastrointestinal disturbances, including nausea and vomiting, dizziness, headache, drowsiness and dry mouth • Psychiatric side effects: nightmares, agitation, rarely confusional state • Other side effects: respiratory depression • Advise that zopiclone should not be taken continuously • Do not drink alcohol when taking zopiclone • Do not drive or operate machinery if affected by zopiclone • Provide a written information leaflet using the following link https://www.choiceandmedication.org/florid-eastlondon/
Follow up	Arranged as part of the assessment and review with HTT and crisis team

Record	Document intervention in patients progress notes on RIO and document the following on the PGD log:
	• Patient's name, address, date of birth and consent given
	• Diagnosis
	• Name of drug and strength of tablet and route
	• Dose and form, frequency and quantity administered and /or supplied.
	• Advice given to patient (including side effects and timing)
	• Date administered and/or supplied
	• Details of any adverse drug reaction and actions taken including documentation in the patient's medical record and reporting to the doctor and/or the Medicines Healthcare Regulatory Authority if appropriate.
	• Referral arrangements (including self-care)
	• Document on the patients prescription chart being used by the team – either paper or electronic that supply under the PGD has been given
	• In the section for 'once only medication'
	• Include the date, drug name, strength, form, dose, quantity of tablets and initials of the nurse supplying under the PGD
	  • Record supply made under PGD.
	  • The issue or administration of zopiclone tablets should be noted during handovers.
	  • A record of medication supply should be included in GP letters

References	Zopiclone 3.75mg Tablets SPC, Mylan, Last Updated on eMC 18/2/22 – changes updated to PGD. British National Formulary Online (NICE) last updated on 18/11/22 Sussex Partnership PGD for the inpatient administration of oral Zopiclone to working age and older people (last updated 21/2/19)

Organisation and individual authorisation signatures can be found on the managerial content sheet along with other non-clinical details relating to this patient group direction.

MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR

Zopiclone 7.5mg tablets

Patient Group Direction Owner	
Details	Name: Maryam Chohan Position: Crisis Pathway Pharmacist Contact Address: Mayer Way, Houghton Regis, LU5 5 BF Contact Telephone: 07768866553 Contact Email: Maryam.chohan1@nhs.net

Patient Group Direction Details	
Date comes into effect	March 2023
Date of expiry + review	March 2026
Staff characteristics	Band 6 or above nurse working in ELFT home treatment team or crisis service who has passed to a satisfactory degree the ELFT psychopharmacology course. Registered Nurse with current Nursing and Midwifery Council registration or Emergency Care Practitioner with current registration with the Health Professions Council, employed by East London NHS Foundation Trust who is assessed and deemed competent and thus authorised to work under this PGD. Access to the current edition of the British National Formulary and the Summary of Product characteristics and any relevant updates required **>> YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING UNDER IT <<**

Patient Group Direction Authorisation	
Chief Medical Director	Name: Dr David Bridle Position: Chief Medical Officer Signature:  Date: 04/05/23
Interim Chief Pharmacist	Name: Andrea Okoloekwe Position: Interim Chief Pharmacist Signature:  Date: 04/05/23
Author	Name: Diksha Malhotra Position: Crisis Pathway Pharmacist, Tower Hamlets Signature:  Date: 18/11/22

Editor	Name: Maryam Chohan Position: Crisis Pathway Pharmacist, Luton & Bedford Signature:  Date: 27/04/23
Chief Nurse	Name: Lorraine Sunduza Position: Chief Nurse Signature:  Date: 04/05/23

MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR
Zopiclone 7.5mg tablets

Individual Authorisation

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT

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. YOU CANNOT DELEGATE TASKS UNDER THIS PGD TO ANYONE ELSE

IF THIS IS AN UPDATED OR REPLACEMENT PGD ENSURE THAT ALL OLDER VERSIONS ARE WITHDRAWN FROM USE WITH IMMEDIATE EFFECT

IT IS YOUR REPONSIBILITY TO MAKE SURE YOU ARE USING THE CURRENT VERSION

NOTE TO AUTHORISING MANAGERS: AUTHORISED STAFF SHOULD BE PROVIDED WITH AN INDIVIDUAL COPY OF THE CLINICAL CONTENT (NON-MANAGERIAL CONTENT PART) OF THE PGD AND A PHOTOCOPY OF THE AUTHORISATION SHEET SHOWING THEIR AUTHORISATION

THE PRACTITIONER MUST BE REGISTERED WITH THE NMC OR THE HPC AND AN EMPLOYEE OF EAST LONDON NHS FOUNDATION TRUST AND WILL ENSURE THAT HE/ SHE HAS THE RELEVANT TRAINING AND IS COMPETENT IN ALL ASPECTS OF THE ADMINISTRATION OF MEDICINES PERTAINING TO THIS PATIENT GROUP DIRECTION, INCLUDING THE CONTRA-INDICATIONS AND THE RECOGNITION AND TREATMENT OF ANAPHYLAXIS. HE/SHE WILL ATTEND UPDATES AS APPROPRIATE.
THIS PRACTITIONER WILL HAVE DUE REGARD FOR THEIR REGULATORY BODY'S STANDARDS OF CONDUCT, PERFORMANCE AND ETHICS.

THIS AUTHORISATION IS VALID FOR THE LIFE OF THE CURRENT DOCUMENT OR UNTIL ANY CHANGES ARE MADE TO IT IN LIGHT OF NATIONAL GUIDANCE.

THE PGD WILL BE REVIEWED IN THE LIGHT OF NEW NATIONAL GUIDANCE

Enquiries relating to this PGD should be addressed to:
Medicines Management Team, East London NHS Foundation Trust, 9 Alie Street, Aldgate, London, E1 8DE

DECLARATION by Nurse/Emergency Care Practitioner:

I have been appropriately trained to understand the criteria listed above and the administration of Zopiclone 3.75mg tablets in accordance with this Patient Group Direction.

Name of Professional	Signature	Registration Number	Date	Authorising Manager

