



Medication Audit Criteria and Guidelines

Non-benzodiazepine Sedative Hypnotics (Receptor Agonist)

- Eszopiclone (Lunesta®)
- Zolpidem (Ambien®)

PEFC Approved: July 2023

Indications

If a medication is prescribed for an off-label indication, documentation in the patient chart is recommended.

Label:

- Difficulties with sleep initiation
- Difficulties with sleep maintenance

Black Box Warning

Complex sleep behaviors including sleepwalking, sleep-driving, engaging in other activities while not fully awake, may occur following use of eszopiclone or zolpidem. Some of these events may result in serious injuries, including death. Discontinue eszopiclone/zolpidem immediately if a patient experiences a complex sleep behavior.

Contraindications

- Complex sleep behaviors after taking as stated above.
- Known hypersensitivities which may include anaphylaxis and/or angioedema.

Warnings and Precautions

- Abnormal thinking and behavioral changes
- CNS - Depressant effects and next day impairment
- Use in debilitated patients
- Use in female patients
- Use in older adult population (65+ years)
- Use in patients with depression
- Use in patients with history of hepatic impairment
- Use in patients with history of respiratory disease (COPD, sleep apnea, etc.)
- Use in patients with Myasthenia gravis (zolpidem)

- Use in patients with history of substance misuse
- Use in pregnant patients
- Withdrawal effects

Adverse Reactions

Side Effects Which Require Medical Attention

- Ataxia
- CNS depression
- Complex sleep behaviors
- Confusion or disorientation
- Drowsiness
- Dysgeusia (eszopiclone)
- Dyspepsia (eszopiclone)
- Falling or dizziness
- Headache
- Nausea (eszopiclone)
- Rash
- Suicidal behavior and ideations
- Withdrawal
- Worsening agitation, disinhibition, or aggression
- Xerostomia (eszopiclone)

Drug Interactions of Major Significance

See: Contraindications

See: [Indiana Univ Drug Interaction Table](#)

See: Lexicomp, Micromedex for more information

Special Populations

- Pediatrics/Adolescents
 - Safety and efficacy have not been established in children younger than 18 years.
 - "Psychotropic Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health (6th Version)" reviewed both eszopiclone and zolpidem but they were not included/recommended.
- Geriatric
 - Included in Beers Criteria, avoid use as potentially inappropriate in older adults.
- Renal: no dosage adjustments needed.
- Hepatic

- ▶ Mild to moderate hepatic impairment: eszopiclone – no dosage adjustment; maximum zolpidem dose 5 mg
- ▶ Severe hepatic impairment: maximum eszopiclone dose 2 mg; avoid zolpidem use
- Hemodialysis
 - ▶ No dosage adjustment needed.
- Pregnancy and Breastfeeding
 - ▶ See Warnings and Precautions.
 - ▶ Review product-specific labeling. Consider risks/benefits in reviewing medication-specific labeling.

Patient Monitoring Parameters

Baseline Tests:

- Pregnancy test (females)
- Assess for signs of respiratory depression

Ongoing Tests:

- Pregnancy test (females) as clinically indicated
- Assess for signs of respiratory depression

Dosing

- See HHSC Psychiatric Drug Formulary for dosage guidelines.
- If a medication is prescribed at dosages in excess of the Psychotropic Dosage Guidelines found in the HHS Psychiatric Drug Formulary, documentation in the patient chart is recommended.