

NON-DRUG INTERVENTIONS AND TIPS

SLEEP HYGIENE

- No caffeine after midday
- No alcohol consumption in late evening
- Regular exercise, but not too late in the day
- Constant wake time, even on weekends
- Limit naps during the day
- Make sure the bedroom is comfortable (*i.e.*, not too hot or too cold), quiet, and dark
- Reserve the bed for sleeping and sexual activity only
- Avoid challenging tasks before bedtime (*i.e.*, puzzles)
- Avoid watching TV, reading, or eating in bed
the resident to eat in the dining area, watch TV, or read in the recreational area whenever possible.
- Limit unpleasant activities right before bedtime
- If unable to sleep after 30 minutes, get up and do a relaxing activity, then once sleepy, lie back in bed and try to sleep as often as necessary.
- Maintain bedtime ritual and consistent as much as possible to promote sleep

OTHER NON-PHARMACOLOGIC THERAPIES

- Cognitive-behavioral therapy
- Sleep restriction therapy
- Stimulus control
- White noise therapy

PHARMACOLOGIC MANAGEMENT OF INSOMNIA

GENERAL

- Drug therapy should only be used after an adequate trial of non-pharmacologic therapies have been instituted.
- Important to choose an agent based on the patient's clinical presentation. *When the patient complains of the inability to stay asleep, an agent indicated for sleep maintenance is preferred.*
- The benzodiazepines and benzodiazepine receptor agonists have a potential adverse effect of “complex sleep-related behaviors” such as sleep-driving, making phone calls, and eating food (*while asleep*). These agents may also cause anaphylaxis and angioedema.⁵

CAUTION: DRUGS TO AVOID IN THE ELDERLY²⁻⁴

These medications are generally avoided in the elderly when treating insomnia. Safer alternatives are available and the risk of adverse effects from these medications is outweighed by the potential benefits of their use:

- | | | | |
|---------------|-----------------|-----------------|-----------------|
| ■ Amobarbital | ■ Glutethimide | ■ Meprobamate | ■ Pentobarbital |
| ■ Arbutamine | ■ Mephobarbital | ■ Phenobarbital | ■ Secobarbital |

DRUGS GENERALLY NOT TO BE USED IN THE ELDERLY²⁻⁴

These drugs are generally NOT to be used in older adults for treating insomnia. The risk of adverse effects from these drugs is not outweighed by their potential benefit for use in insomnia:

- Anticholinergics; due to high potential of anticholinergic adverse effects
- Antipsychotics; due to high potential of anticholinergic adverse effects and residual daytime drowsiness/excessive somnolence
- Hypnotics; due to high potential of anticholinergic adverse effects and residual daytime drowsiness/excessive somnolence
- First-generation antidepressants; due to active metabolites causing residual daytime drowsiness/excessive somnolence
- Quaalupam; due to active metabolites causing residual daytime drowsiness/excessive somnolence

PHARMACOLOGIC MANAGEMENT OF INSOMNIA (Continued)

MEDICATIONS USED TO TREAT INSOMNIA IN THE ELDERLY

DRUG	DOSAGE	HALF-LIFE	MECHANISM OF ACTION	INDICATIONS	COMMON ADVERSE EFFECTS
Benzodiazepines					
Estazolam ¹⁰	0.5 mg at bedtime	13.5 - 34.6 hours (mean 18.4 hours)	Increased GABA activity by possible binding to GABA receptors	Sleep onset or Sleep maintenance	Somnolence, daytime cognitive impairment, motor coordination, risk of falls, anterograde amnesia, dependence
Temazepam ¹⁰	15 mg at bedtime	3.5 - 18.4 hours (mean 8.8 hours)		Duration of use: Short-term (7-10 days)	
Non-Benzodiazepine Hypnotics					
Zolpidem IR ¹⁰ (Ambien®)	5 mg at bedtime	3 hours	Imidazopyridine that selectively binds to alpha 1/5 subunit of the benzodiazepine receptor of GABA(A)	Sleep onset and/or Sleep maintenance	Somnolence, difficulty with coordination, anaphylaxis, angioedema
Zolpidem ER ^{6,10} (Ambien CR®)	6.25mg at bedtime	3 hours	Same as Zolpidem IR	Sleep onset and/or Sleep maintenance	Headache, somnolence, dizziness, difficulty with coordination, anaphylaxis, angioedema
Zaleplon ^{7,10} (Sonata®)	5 mg at bedtime	1 hour	Imidazopyridine that binds to alpha 1 subunit of the benzodiazepine receptor of GABA(A)	Sleep onset	Somnolence, dizziness, lightheadedness, difficulty with coordination, anaphylaxis, angioedema
Eszopiclone ^{8,10} (Lunesta®)	Sleep latency: 1mg at bedtime Sleep maintenance: 2mg at bedtime	3 hours	Imidazopyridine that interacts with GABA receptor on complexes located close to the benzodiazepine receptors	Sleep onset and/or Sleep maintenance	Headache, somnolence, unpleasant taste, dry mouth, anaphylaxis, angioedema
Ramelteon ^{9,10} (Rozerem®)	8 mg at bedtime	7-9 hours	Binds to melatonin-1 and melatonin-2 receptors, thereby mimicking the role of endogenous melatonin in the normal sleep-wake cycle	Sleep onset	Somnolence, dizziness, headache, nausea, anaphylaxis, angioedema

Restrictions EXCEPT ramelteon

* Maximum daily dosage threshold according to CMS is 1 mg.

OFF-LABEL USE OF MEDICATIONS TO TREAT INSOMNIA¹

are not FDA approved for insomnia. There have been no well-designed (randomized, double-blind) studies demonstrating effectiveness in treating primary insomnia.

- **Zolozone:** Commonly used at low doses for insomnia complaints. May be useful in patients with secondary insomnia caused by depression. May cause orthostatic hypotension.
- **Quetiapine:** Used at low doses for insomnia complaints. May cause extrapyramidal symptoms and metabolic adverse effects such as hyperglycemia and weight gain.

Useful Websites for Additional Information: National Sleep Foundation: www.sleepfoundation.org
World Sleep Foundation: www.worldsleepfoundation.com

TREATING INSOMNIA IN SKILLED NURSING FACILITIES

SPECIAL CONSIDERATIONS

On December 18, 2006, the Centers for Medicare & Medicaid (CMS) implemented new survey guidelines for Pharmacy and Unnecessary Medication (F-Tag 329) in Appendix P and PP of the State Operations Manual. While F329 guidance document emphasizes the importance of seeking an appropriate dose and duration for each medication, reduction (GDR)/tapering is still mentioned for specific classes of medication including sedative-hypnotics.

Daily Dose Thresholds For Sedative-Hypnotic Medications

Adapted from: State Operations Manual. Centers for Medicare & Medicaid Services. Appendix PP, Tag F329.

Generic Medications	Oral Dosages	Generic Medications	Oral Dosages
Chloral Hydrate*	500mg	Hydroxyzine *	50mg
Diphenhydramine*	25mg	Lorazepam	1mg
Estazolam	0.5mg	Oxazepam	15mg
Eszopiclone	1mg	Quazepam *	7.5mg
Flurazepam *	15mg	Ramelteon	8mg

*These medications are not considered medications of choice for the management of insomnia in long-term care individuals.

Gradual Dose Reduction/Tapering For Sedatives-Hypnotics

Adapted from: State Operations Manual. Centers for Medicare & Medicaid Services. Appendix PP, Tag F329.

Applicable Medications	Any medication that is being used for the treatment of insomnia. Examples include: <ul style="list-style-type: none"> • Benzodiazepines • Chloral hydrate • Eszopiclone • Zaleplon
Conditions that Must be Present for GDR/Tapering	Used routinely for the treatment of insomnia. Recommendations for duration of use.
Indications Involving GDR/Tapering	All
Exempted Indications	Not applicable.
Frequency	Quarterly (every 3 months)
Clinical Contraindications	Contraindications in accordance with relevant current standards of practice, and physician has documented clinical rationale. -OR- Symptoms returned or worsened after MOST RECENT GDR attempt WITHIN 30 days and physician has documented clinical rationale.

References

1. Balcer, et al. Sleep medicine: a pathophysiologic approach. Seventh edition. New York: McGraw-Hill, 2008. Chapter 75.
2. Flkholy, et al. Sleep and aging: 2. management of sleep disorders in older people. CMAJ. 2007;176:1449-1454.
3. Principles and practice of geriatric medicine, fourth edition. West Sussex, England: John Wiley & Sons Ltd., 2006. pp.733-740.
4. et al. Updating the Beers criteria for potentially inappropriate medication use in older adults. Arch Intern Med. 2003;163:1623-1631.
5. FDA label change for all sleep disorder drug products. [Internet] Rockville (MD). www.fda.gov/bbs/topics/NEWS/2007/NEW01587.html
6. Ambien CR® (zolpidem tartrate extended-release). sanofi-aventis U.S. LLC; Bridgewater, NJ; 2009.
7. Information: Sonata® (zaleplon). Wyeth Pharmaceuticals, Inc; Philadelphia, PA; 2008.
8. Information: Lunesta® (eszopiclone). Sepracor Inc.; Marlborough, MA; 2009.
9. Product Information: Rozerem® (ramelteon). Takeda Pharmaceuticals America, Inc; Deerfield, IL; 2009.
10. Lexi-Comp Online™, Geriatric Lexi-Drugs Online™, Hudson, Ohio: Lexi-Comp, Inc.; 2010; January 29, 2010.

All sections refer to 1-3 unless otherwise indicated

Form # A99147RCK

© 2007 American Society of Consultant Pharmacists

© 2007 American Society of Consultant Pharmacists



AMERICAN SOCIETY OF
CONSULTANT PHARMACISTS
1321 Duke Street, Alexandria, VA 22314-3563
E-mail info@ascp.com • www.ascp.com

America's Senior Care Pharmacists®

Content edited and updated by
Jaime L. Caputo, PharmD Candidate and
Charlie Waters, PharmD, BCPS, CGP, FASCP

Exclusively Distributed By:
MED-PASS
The Fine Art of Document Design
www.med-pass.com