

## Pharmacologic Management of Insomnia



Pre-presentation Survey:  
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URL: <https://www.pcmg-us.org/survey/pre/insomnia7>



# Pharmacologic Management of Insomnia

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Executive Director  
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## Disclosures

- **Stephen Brunton, MD, FAAFP, CDCES**, has disclosed that he is on the advisory board and/or speakers bureau for Abbott Diabetes, AstraZeneca, Bayer, Biolinq, Boehringer Ingelheim, Lifescan, Lilly, Novo Nordisk, Sanofi, and holds stock options for Paracrine.
- All relevant financial relationships have been mitigated.



# Learning Objectives

## Participants in this presentation should be able to...

**Describe** the physiology of sleep and wake as it relates to insomnia management.

**Identify** patients with insomnia by routinely asking about sleep and associated symptoms, as well as employing recommended diagnostic methods.

**Select** appropriate pharmacologic treatments for patients with insomnia, when indicated, based on patient characteristics and risk-benefit profiles.

**Incorporate** DORAs into the multimodal treatment approach for treating insomnia, as appropriate.



## Pathophysiology of Insomnia

- Ascending reticular system (ARAS) drives wakefulness
- Ventrolateral preoptic (VLPO) nucleus influences sleep



Levenson et al. Chest 2015;147:1179-1192  
Robinson CL et al. Health Psychol Res 2022;10



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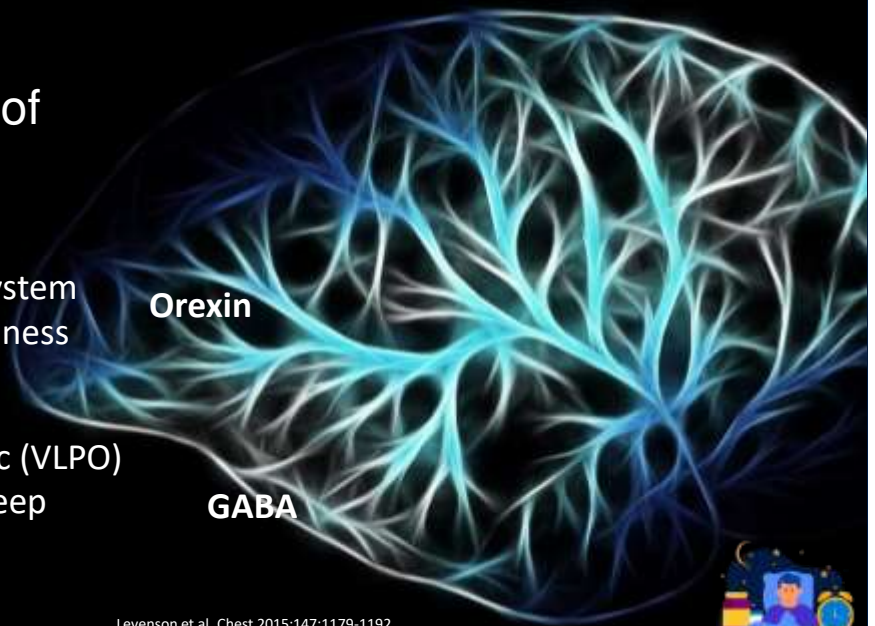
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**GABA**

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Orexin

GABA

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# The Numbers.... What are They?

50

100  
billion

30

10

Gallop Organization for the National Sleep Foundation: 2022



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Percentage of primary care patients reported to experience insomnia

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Percentage of patients who mention this problem to their PCC

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100 billion

Direct and indirect cost of insomnia in United States

Percentage of patients who meet criteria for chronic insomnia

10



Gallop Organization for the National Sleep Foundation: 2022

# Strategies to Combat Episodic Insomnia



[www.thensf.org](http://www.thensf.org)



## Strategies to Combat Episodic Insomnia

- What is good sleep hygiene?
  - Consistent wake/bedtime in cool, dark environment
  - Allowing 7-9 hours nightly
  - Avoiding substances/food/activities before bed
  - Avoiding electronics an hour before bed and never in the bed

[www.thensf.org](http://www.thensf.org)





# What is Insomnia Disorder?



3  
months

- Frequent and persistent difficulty initiating or maintaining sleep

- Reports daytime symptoms

Amer Psych Assoc. Diagnostic and statistical manual of mental disorders (5th ed) 2015



# Consequences of Insomnia

- Disability or medical leave
- Traffic accidents
- Depression, anxiety, alcohol use disorder, psychosis
- Alzheimer's disease
- Hypertension and cardiovascular disease, can be bidirectional
- Death

Deak et al. Neurolog Clin 2012;30(4):1045-66, JAMA 2013;309(7):706-16, Lancet 2012;379:1129-41



# How to Assess for Insomnia

- Ask!

*Do you have trouble getting to sleep or staying asleep?*

*Do you feel well rested during the day?*

- Identify medical and psychiatric comorbidities
- Sleep diary
- Insomnia Severity Index, Pittsburgh Sleep Quality Index, Epworth Sleepiness Scale



# Patient Evaluation of Sleep Disturbance

## Comorbidities

Mental disorders  
Cardiovascular diseases  
Respiratory diseases  
Rheumatologic diseases  
Malignancies  
Endocrine disorders  
Neurogenerative disorders

## Substance Use/ Dependence

Alcohol  
Nicotine  
Caffeine  
THC  
Opioids  
Cocaine  
Amphetamines

## Medications

ADHD stimulants  
SSRIs/ SNRIs  
Bupropion  
Varenicline  
Corticosteroids





## Meet Mrs L

- Mrs L is a 64-year-old patient you have seen for 15 years. She has a past medical history of hypertension and depression, both currently well controlled on amlodipine 10mg-HCTZ 12.5mg daily and sertraline 100mg daily. She recently started a new job as a bus driver for the elementary school since the passing of her husband 6 months ago.
- During her visit today, she mentions to you how tired she is and that she is not sleeping well. After further discussion, you talk briefly about sleep hygiene, ask her to complete a sleep diary and return in 2-3 weeks...



**WEEK 1** Start date:     /    /    

### COMPLETE WHEN YOU WAKE UP

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	
I went to bed at: (circle the time and write am or pm)	9 am	8 am	9 am	8 am	9 am	10 am	9 am
When I went to bed, I felt asleep: (circle one) 1 = With difficulty, 2 = After some time, 3 = Easily	1	3	3	1	2	3	3
I woke up during my sleep: (circle # of times and # of minutes)	# times: 1 # min: 20	# times: 1 # min: 15	# times: 2 # min: 15	# times: 1 # min: 20	# times: 2 # min: 15	# times: 0 # min: 20	# times: 1 # min: 20
I got out of bed at: (circle the time and circle am or pm)	5 am	4 am	5 am	4 am	5 am	6 am	6 am
I slept a total of: (circle approximate hours/minutes)	6	5	6	5	6	6	6
My sleep was disturbed by: (list any factors that made it harder to breathe deep including noise, lights, pets, allergies, temperature, pain, stress, medications, etc.)	tem p						
When I woke up, I felt: (circle one) 1 = Not tired, 2 = Somewhat tired, 3 = Very awake	1	3	3	1	2	3	3

### COMPLETE AT BED TIME

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
I exercised at least 30 minutes AT: (circle all that apply) <input type="checkbox"/> Morning <input type="checkbox"/> Afternoon <input type="checkbox"/> Evening						
Medications I used today:						
		Tylenol PM		melatonin	melatonin	melatonin
I took a nap today: (circle YES or NO, if YES, write how long you napped)						
YES NO	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
X	X	X	X	X	X	X
How likely was I to dose off while doing daily activities today: (circle one) 1 = Not at all likely, 2 = Not very likely, 3 = Somewhat likely, 4 = Very likely						
1	3	4	3	4	1	4
My mood today was: (circle one) ☺ = Good   ☹ = Okay   ☹☹ = Poor						
☹☹	☹☹	☹☹	☹☹	☹☹	☹☹	☹☹
Approximately 2-3 hours before going to bed I drank/ate: (circle all that apply) <input type="checkbox"/> Water <input type="checkbox"/> Tea/Herbal tea <input type="checkbox"/> Coffee						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I drank/ate something with caffeine at: (circle all that apply) <input type="checkbox"/> Morning <input type="checkbox"/> Afternoon <input type="checkbox"/> Evening						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
In the hour before going to sleep, my bedtime routine included: (e.g. read books, used electronics, took bath, did relaxation exercises, etc.)						
bath phone	bath phone	bath phone	bath phone	bath	bath	bath



## Return Visit...

- Mrs L completed her sleep diary and started taking melatonin supplements (5mg) during second week with no noticeable improvement.
- Upon questioning, she admits to scrolling through her social media in bed when she is frustrated about not sleeping, and sleeps with TV on with sound very low.
- Tylenol PM (taken once) caused excessive sleepiness the next day.
- Her PHQ-9 score is 8; she admits to being lonely but otherwise ok.



# What is First Line Treatment?

Edinger J et al. J Clin Sleep Med 2021;17(2):255-262





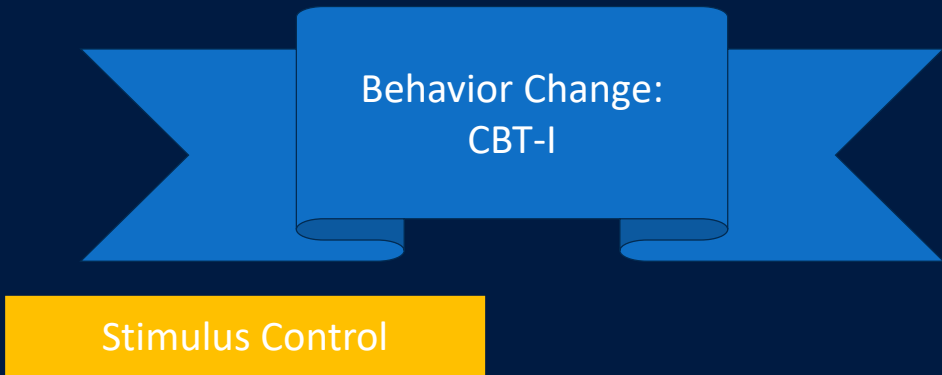
# What is First Line Treatment?

Behavior Change:  
CBT-I

Edinger J et al. J Clin Sleep Med 2021;17(2):255-262



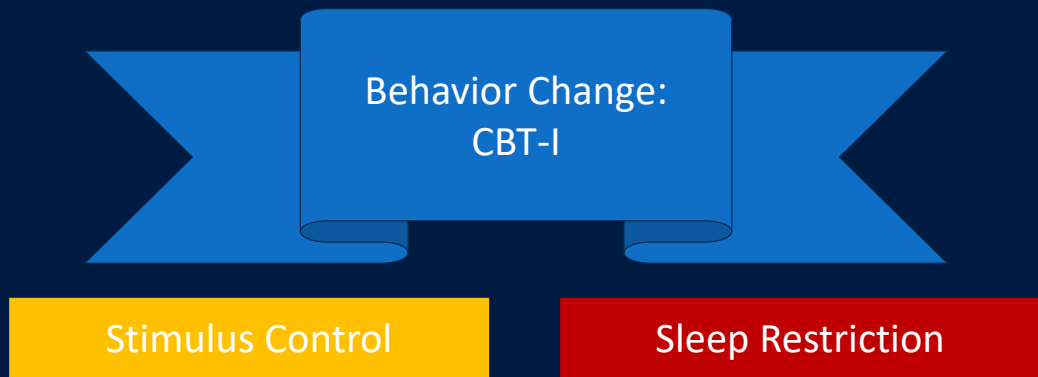
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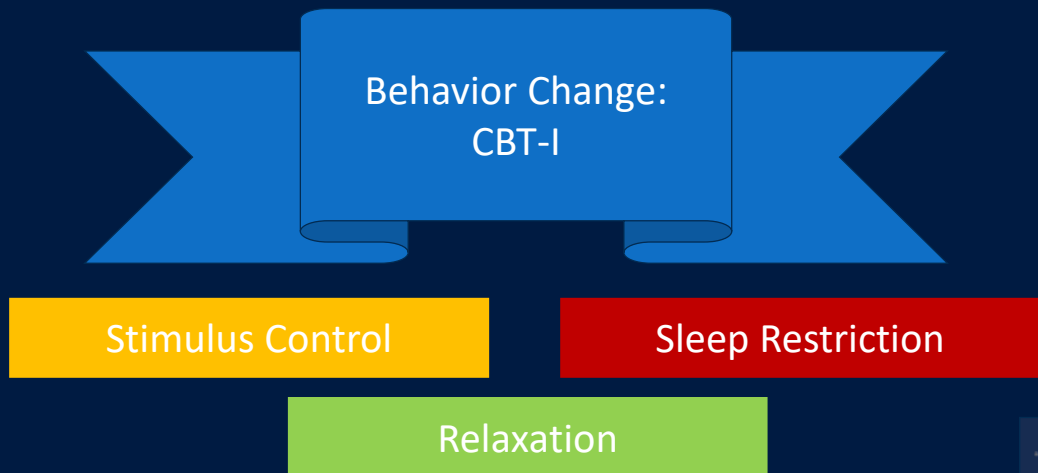
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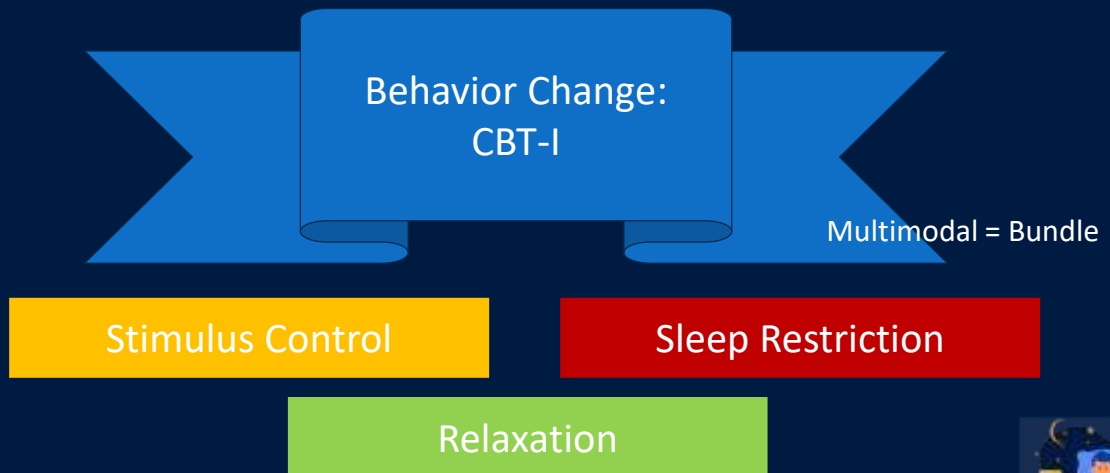
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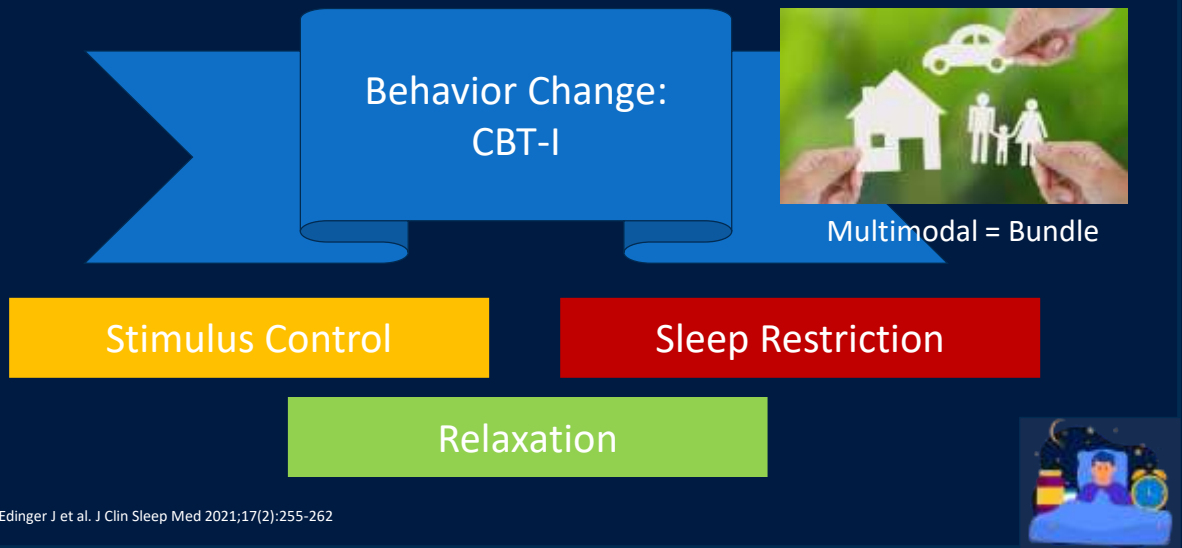


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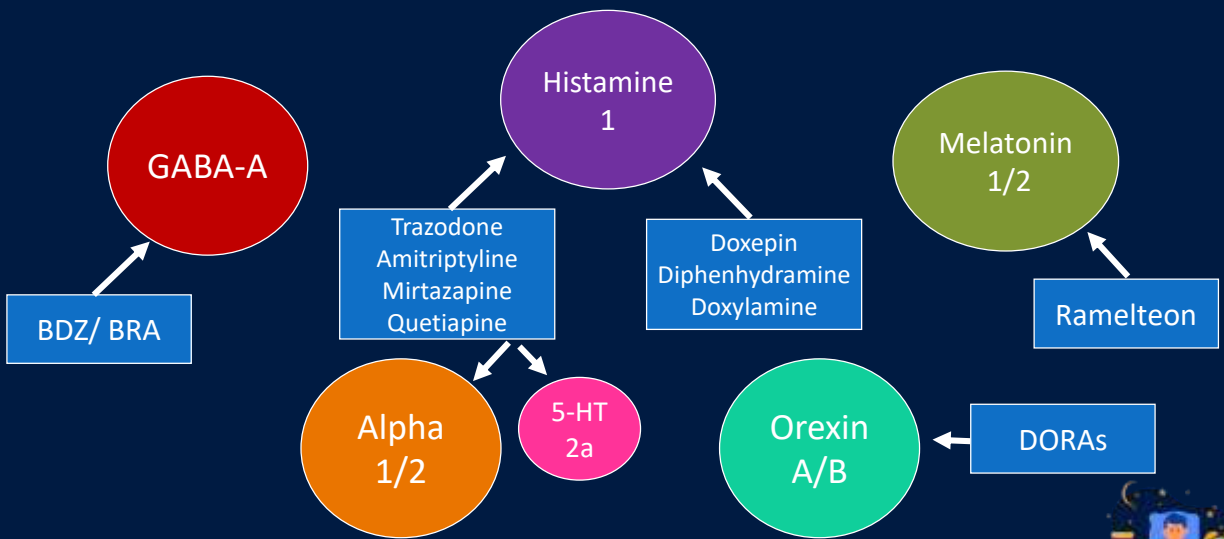


## And if CBT-I Doesn't Work?

Commonly Used Medications for Sleep	
<b>Sedating antidepressants</b>	<b>Antipsychotics</b>
trazodone, doxepin, mirtazapine	quetiapine
<b>Melatonin agonist</b>	<b>Herbal supplements</b>
ramelteon	melatonin, L-tryptophan, valerian, chamomile
<b>Benzodiazepine receptor agonists</b>	<b>Antihistamines</b>
zolpidem, eszopiclone, zaleplon	diphenhydramine, doxylamine
<b>Benzodiazepines</b>	<b>Anticonvulsants</b>
temazepam, clonazepam, alprazolam	tiagabine
<b>Dual orexin receptor antagonists</b>	
suvorexant, lemborexant, daridorexant	



# Receptor Breakdown for Sleep



Verduzco et al. Ment Health Clin 2023;13(5):244-54





## The Orexin Story



- Orexin (ORX-A and ORX-B) are neuropeptides discovered in 1998
- Involved in central physiological regulation of sleep and wakefulness, and maintenance of arousal
- Dual orexin receptor antagonists (**DORAs**) are FDA-approved for treatment of insomnia
  - Suborexant (2014)
  - Lemborexant (2019)
  - Daridorexant (2022)



Pizza F et al. J Sleep Res 2022;31:e13665

## What to Know about DORAs

- Pharmacokinetic half-life differences:
- Suvorexant 12 hours
- Lemborexant 18 hours
- Daridorexant 8 hours

- Work by reducing arousal but preserve person's ability to awaken in response to auditory stimuli
- FDA-approved for sleep onset and sleep maintenance insomnia
- Studies up to 3 months show continued efficacy, low risk of rebound insomnia upon discontinuation
- Next day cognition data is positive



# DORA Counseling

## Dosing

Suvorexant	10mg, 30 min before bedtime
Lemborexant	5mg immediately before bedtime
Daridorexant	25-50mg within 30 min before bedtime



## Adverse Effects

**Headache**  
**Dizziness**  
**Daytime sleepiness**  
**Sleep Paralysis**  
**Hypnagogic hallucinations**  
**Suicidal Ideations**

## Additional Info

- **Contraindication: Narcolepsy**
- **Do not use in severe liver impairment & sleep apnea**
- **DORAs are CYP 3A4 substrates**
- **Time to sleep delayed with high-fat meal**
- **Schedule IV medicine**
- **Expensive**



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# Zzzzzzzz Drugs: Important Points

	Dosing	Unique Considerations
Zolpidem	IR or nasal spray: Men: 5-10mg Women: 5mg ER formulation: Men: 6.25-12.5mg Women: 6.25mg Elderly: 5mg	Visual disturbances Slower clearance in women and elderly ER: Do not perform next day activities requiring complete awareness
Eszopiclone	1 to 2mg	Unpleasant taste
Zaleplon	5 to 10mg	Shortest half-life: 1 hour Sleep onset approval only

- Minimal anxiolytic effects compared to BDZ
- Lower risk of tolerance, abuse, dependence when compared to BDZ
- Short-term use (< 4 weeks) recommended



## Z Drug Warnings and ADRs

**Black Box Warning (2019): complex sleep disorders such as sleepwalking and sleep driving can result in serious injury or death**

### Adverse Effects

Headache, dizziness, confusion, next-day drowsiness, falls, amnesia, rebound insomnia, withdrawal





## Remember This Survey Question?



Zolpidem 10mg at night is most appropriate for

- A. 45-year-old man with heart disease.
- B. 67-year-old female currently taking melatonin for sleep.
- C. 40-year-old who drinks alcohol (1-2 drinks) most evenings.
- D. 29-year-old truck driver.

A 10mg dose of zolpidem is not recommended in women or elderly (at least initially), should not mix with alcohol at all (increased risk of complex sleep behaviors), and should not be used for patients who require next day alertness for their job (like a commercial driver).



## BDZs: Temazepam, Triazolam

Indicated for short-term treatment of insomnia (2 weeks)

### **Not generally recommended due to adverse effect potential:**

- Next day fatigue
- Anterograde amnesia
- Depression (longer term use)
- Falls and fracture risk (on Beer's list of unsafe medications in elderly)
- CNS additive effects with alcohol
- Abuse potential

Verduzco A et al. Ment Health Clin 2023;13(5):244-54



## My Circadian Rhythm Needs Help!

- Ramelteon has 3 to 5 times the selective affinity for melatonin receptors
- FDA-approved for sleep onset insomnia



- Well tolerated
  - Safe with substance use disorders
  - Can cause next day drowsiness
- Generic now available
- Dose: 8mg at bedtime



# Sedating Antidepressants



## Sedating Antidepressants

Doxepin

- ❑ Tricyclic antidepressant (traditional doses of 75mg daily)
  - At low doses (3-6mg nightly), has strong binding to histamine-1; no other neurohormones binding
    - FDA-approved for sleep maintenance insomnia
      - ❑ Well tolerated and very low risk of next day impairment

Shaha D. J Fam Practice 2023;72(6):S31-36, Verduzco A et al. Ment Health Clin 2023;13(5):244-54



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  - At doses <100mg, inhibits 5-HT<sub>2A</sub>, H<sub>1</sub>, and alpha to produce hypnotic effects
    - Limited evidence on efficacy or safety for insomnia

### Trazodone



Shaha D. J Fam Practice 2023;72(6):S31-36, Verduzco A et al. Ment Health Clin 2023;13(5):244-54

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### Trazodone

### Mirtazapine

- ❑ Atypical antidepressant that enhances release of serotonin, and antagonizes histamine receptors at low doses (15mg)
  - Sedation reported in 50% patients in treatment of depression
    - No studies in insomnia available

Shaha D. J Fam Practice 2023;72(6):S31-36, Verduzco A et al. Ment Health Clin 2023;13(5):244-54



## How is Mrs L doing?

- During her follow-up visit, Mrs L agreed to stop scrolling through her phone in bed and try to sleep with TV off.
- Upon return 1 month later, she reports no phone/TV for an hour before bed, and instead started listening to white noise.
- She joined a local gym and started a senior adult class 4 days per week at 5pm, which has helped with her loneliness.
- Her sleep diary still shows only 5 to 6 hours of sleep nightly and she reports increased fatigue during the daytime.





## Do We Have Good Guidance?

2017 AASM		2019 VA/DoD	
<b>Strong for: CBT-I (mod-qual)</b>		<b>Strong for: CBT-I</b>	
<b>Weak for:</b> Temazepam Eszopiclone Zolpidem	Zaleplon Ramelteon Triazolam Doxepin Suvorexant	<b>Weak for:</b> Doxepin Z-drugs	<b>Weak Against:</b> Diphenhydramine Melatonin Antipsychotics BZDs Trazodone
<b>Not Recommended:</b> Diphenhydramine Melatonin Trazodone		<b>Neither for or Against:</b> Ramelteon Suvorexant <b>Strong Against:</b> Kava	



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## Guideline Update 2023: Europeans

### Strong for: CBT-I (A)

#### < 4 weeks:

BDZ/BRA (A)

Daridorexant (A)

Low-dose antidepressants (B)

#### 3 months:

DORAs (A)

Ramelteon (B)

### **Not Recommended:**

Antihistamines

Antipsychotics

Melatonin

J Sleep Res 2023;32:e14035



## Specific Patient Considerations

	Sleep-onset insomnia	Sleep maintenance insomnia	Vulnerability to substance disorder	Need for normal next-day function
DORAs	X	X	X	X
BDZ		X		
BRA*	X	X		
Doxepin		X	X	X
Ramelteon	X		X	

Shaha D. J Fam Practice 2023;72(6):S31-36, Rosenberg R et al. Prim Care Companion CNS Disord 2023;25



## Remember This Knowledge Question?

What is a medication shown to improve sleep onset, sleep maintenance, and have a low risk of next day impairment and rebound insomnia or withdrawal?

- A. trazodone
- B. ramelteon
- C. daridorexant
- D. No such medicine exists

Trazodone is not well studied in insomnia, not FDA-approved, efficacy is doubted, and safety is unknown. Ramelteon is not FDA-approved for sleep maintenance and guidelines differ on efficacy recommendations (still better than OTC melatonin). Early clinical trials with daridorexant have indicated improved sleep onset, improved sleep maintenance and a low risk for the negative impacts described above.



## Back to Mrs L

- At last visit, Mrs L was encouraged for making hard lifestyle changes and encouraged to continue. She also agreed to a sleep restriction trial during school Spring break (stayed up until midnight and got up at 6am, then increased bedtime by 30 minutes every night).
- She has returned 1 month later and reports improvement, but still struggling several nights per week and has fatigue during daytime, making it difficult to attend gym classes.
- You discuss medication to assist with insomnia...







## You Choose

Based on the guidelines, what medication has the highest evidence for efficacy and safety for Mrs L?

- a. Trazodone
- b. Daridorexent
- c. Doxepin
- d. Ramelteon





## Correct Answer

### Daridorexent

Based on sleep onset and sleep maintenance issues, and a need for early morning alertness for her job, B is the correct answer.

Another acceptable option would be doxepin 3mg with close follow up, but it is not great for sleep onset. The shortest acting BRA zaleplon could be a short-term option as well.





I'm almost done....  
**WAKE UP!**





I'm almost done....  
**WAKE UP!**

- Discuss sleep with your patients





## I'm almost done.... **WAKE UP!**

- Discuss sleep with your patients
- Counsel on good sleep behaviors and strategies





## I'm almost done.... WAKE UP!

- Discuss sleep with your patients
- Counsel on good sleep behaviors and strategies
- Carefully select appropriate patients for pharmacologic treatment IN ADDITION to behavior change





## I'm almost done.... WAKE UP!

- Discuss sleep with your patients
- Counsel on good sleep behaviors and strategies
- Carefully select appropriate patients for pharmacologic treatment IN ADDITION to behavior change
- Follow-up with all patients!



## Resource Toolkit

- More resources for you on insomnia can be found at our resource toolkit, which you can visit via the URL or QR Code below.
- You'll also find a video of this presentation if there is anything you wish to review.



<https://www.pceconsortium.org/toolkit/insomnia>





# Learning Objectives

**Let's go over the learning objectives we covered in this presentation:**

**Describe** the physiology of sleep and wake as it relates to insomnia management.

**Identify** patients with insomnia by routinely asking about sleep and associated symptoms, as well as employing recommended diagnostic methods.

**Select** appropriate pharmacologic treatments for patients with insomnia, when indicated, based on patient characteristics and risk-benefit profiles.

**Incorporate** DORAs into the multimodal treatment approach for treating insomnia, as appropriate.



## Pharmacologic Management of Insomnia



Post-presentation Survey:  
Please complete the brief  
survey by using the QR  
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URL: <https://www.pcmg-us.org/survey/post/insomnia7>

