

Name(s)

- **Generic:** zolpidem (zole PI dem) | **Brand:** Ambien, Ambien CR, Edluar, Intermezzo, Zolpimist

Therapeutic Category

- Hypnotic | Selective Benzodiazepine-1 Receptor Agonist

Indication(s)

1. **Insomnia:** For short-term use defined as ≤ 4 -8 weeks and ideally used w/ nonpharmacologic therapies. Used for Sleep-onset insomnia, Sleep-maintenance insomnia (7-8 hours planned sleep), Sleep-maintenance insomnia if awakening w/ 4 hours planned sleep

Dosage Form & Strength

- **Dosage Forms:**
 - **Tablet, Immediate Release (IR):** 5 mg, 10 mg
 - **Tablet, Extended Release (ER):** 6.25 mg, 12.5 mg
 - **Tablet, Sublingual (SL):** Edluar (5 mg, 10 mg); Intermezzo (1.75 mg, 3.5 mg)
 - **Solution:** Zolpimist (5 mg/actuation)

Dosing by Indication

- **Dosing Adults w/ Sleep-onset OR maintenance Insomnia:**
 - **ER tablet:** Initiate 6.25 mg if female and 6.25-12.5 mg if male immediately before bedtime. Patient must have 7-8 hours of planned sleep before waking. DNE 12.5 mg
 - **IR tablet, spray, sublingual tablet (OFF-LABEL dosing if for maintenance use):** Initiate 5 mg if female or 5-10mg immediately before bedtime. Patient must have 7-8 hours of planned sleep before waking. DNE 10 mg
- **Dosing Adults w/ Sleep-maintenance Insomnia (if awakening w/ 4 hours of planned sleep):**
 - **IR sublingual tablet:** Initiate 1.75 mg if female or 1.75-3.5 mg if male once per night upon awakening if middle of night as long as there is at least 4 hours of planned sleep remaining.
- **Discontinuation of therapy** consideration is very important for patients taking higher doses (10-12.5 mg/day) for an extended period of therapy. Taper down slowly such as 25% reductions each week of every other week.
- **Dosing Pediatrics w/ Insomnia:**
 - **Children and Adolescents ≤ 17 years:** Important to note that there is limited data available and the lowest effective dose should be used.
 - **Weight based dosing** of 0.25 mg/kg w/ a max dose of 10 mg/dose has been used in prior studies.
 - **IR tablet, spray:** Initiate 5 mg in females and 5-10 mg in males immediately before bedtime with a max dose of 10 mg/dose
 - **ER tablet:** Initiate 6.25 mg in females and 6.25-12.5 mg in males immediately before bedtime with a max dose of 12.5 mg/dose
 - **SL tablet:**
 - Edluar is initiated at 5-10 mg (5 mg if female) immediately before bedtime with a 10 mg/dose max.
 - Intermezzo is initiated at 1.75-3.5 mg (1.75 mg if female) upon awakening if at least 4 hours left before waking. Max 1.75 mg/night in females and 3.5 mg/night in males

Mechanism of Action & Pharmacology

- **MOA:** Zolpidem works through selective benzodiazepine-1 (BZ1) receptor agonism through enhancing the inhibitory neurotransmitter gamma-aminobutyric acid (GABA). The BZ1 receptor selectivity over BZ2 minimizes anticonvulsant, anxiolytic, and myorelaxant properties which are generally contributed to BZ2 receptor agonism. Sedative and hypnotic effects are due to an



increase of chloride conductance, neuronal hyperpolarization, action potential inhibition, and neuronal excitability being decreased.

- **Absorption:** Cmax and AUC increased ~45% in females | **Metabolism:** Hepatically metabolized primarily through CYP3A4 (60%), CYP2C9 (22%), CYP1A2 (14%); and to a lesser extent CYP2D6 (3%), CYP2C19 (3%) | **Excretion:** 48-67% excreted in the urine with 29-42% excreted fecally | **Onset of Action:** IR is 30 minutes | **Time to Peak:** In ages 2-6 years IR is 0.9 hours; In ages >6-12 years IR is 1.1 hours; In adolescents IR is 1.3 hours; In adults IR is 1.6 hours (2.2 hours w/ food), ER is 1.5 hours (4 hours w/ food), Spray/Soln is 0.9 hours, SL (Edluar) is 1.4 hours (1.8 hours w/ food); (Intermezzo) is 1.3 hours (3 hours w/ food) | **Duration of Action:** 6-8 hours | **Half-Life Elimination:** In children varies from 1.8 hours to 2.3 hours; In adults 1.4-4.5 hours and up to 8.4 hours as spray | **Protein Binding:** 93%

Special Populations / Considerations

- Increased Half-Life Elimination in **Elderly** (32%)
- **Hepatically Impaired Patients:** Cmax and AUC 2-5 times higher compared to patients w/ healthy hepatic function. Increased t_{1/2} in patients w/ cirrhosis (9.9 hours, compared to 1.4-4.5 hours, 8.4 hours if spray)
- **Gender (females):** Cmax and AUC higher in women compared to men
- Avoid use in **geriatric** population
- Do not use if **pregnant** or suspected **pregnancy**. Crosses placenta. Severe respiratory depression and sedation in neonates and children born may have withdrawal symptoms.

Side Effects

- **Main (>10%):** Dizziness, headache, drowsiness
- **Others (<10%):** chest pain, increased blood pressure, hallucinations, disorientation, fatigue, memory impairment, depression, vertigo, confusion,
- Abnormal hepatic fxn tests (increased ALT/AST, bilirubin)

BLACK BOX WARNING: Complex Sleep Behaviors – Sleep-walking, sleep-driving, and other activities while not fully awake may occur which may lead to serious injuries including death. D/c immediately if complex sleep behaviors occur.

Drug Interactions

- Azelastine, brimonidine (topical), buprenorphine, cannabis, and others; may enhance CNS depressant effects of zolpidem
- Ciprofloxacin may increase serum concentrations of zolpidem.
- CYP3A4 inducers/inhibitors

Monitoring Parameters

- Watch for complex sleep behaviors, daytime alertness, fall risk, respiratory rate, tolerance, abuse and dependence, pregnancy

Patient Counseling Information

- Take on empty stomach
- Once a night usage taken immediately before going to sleep
- Intended for short-term usage so re-evaluate periodically
- Consult Pbr immediately if trouble breathing, a change in memory or thinking, or if complex sleep behaviors develop.
- Sublingual tablets are to be dissolved under tongue w/o the use of water
- If the pump was prescribed and it has not been used for 14 days or more, you must re-prime it with 1 pump

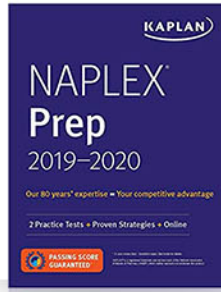
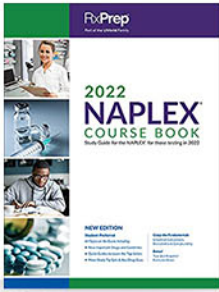
Reference(s)

- <https://www.drugs.com/ppa/zolpidem.html>
- <https://www.webmd.com/drugs/2/drug-8862-8110/zolpidem-oral/zolpidem-oral/details>

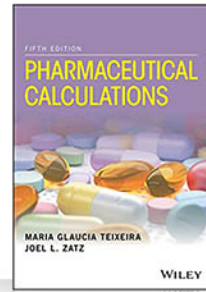
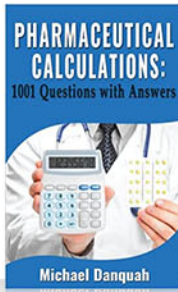
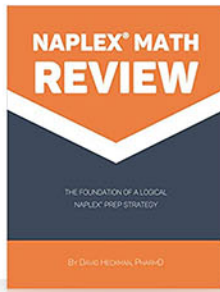
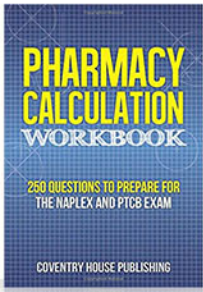


PREPARE FOR SUCCESS!

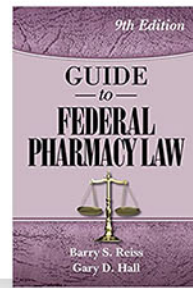
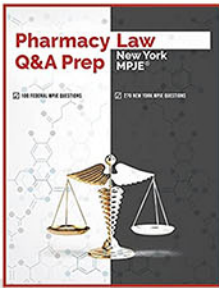
Comprehensive (NAPLEX)



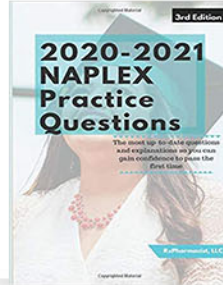
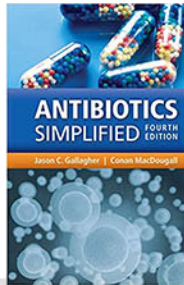
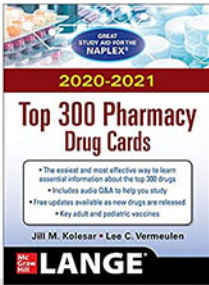
Calculations (NAPLEX)



Pharmacy Law (MPJE)



Supplemental



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So you landed that perfect job offer or got the perfect match for your PGY1 and now the **ONLY** thing standing in your way is passing the NAPLEX and MPJE.

Here are some NAPLEX & MPJE prep recommendations to help you do everything you can to **pass the first time!**

HEY STUDENT!

When I was P1 one of the best pieces of advice I got from those before me was to use a NAPLEX Prep book while learning each topic.

This helps focus your learning and the repetition helps to retain info and indirectly prepare you for the NAPLEX



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