

Sleep on
Demand...



...with

ZOLPIGRESS

Zolpidem Controlled Release Tablets 12.5 mg

la Renon[®]

ZOLPIGRESS™

Zolpidem Controlled Release Tablets 12.5 mg

BACKGROUND:

Sleep is a basic human need and is essential for good health, good quality of life and performing well during the day.

The three elements of good quality sleep are:

1. Duration- The length of sleep should be sufficient for the sleeper to be rested and alert the following day.
2. Continuity- Sleep cycles should be seamless without interruption.
3. Depth- Sleep should be deep enough or sufficiently sound to be restorative and refreshing.

Sleep deprivation causes physical effects (sleepiness, fatigue, and hypertension) cognitive impairment (deterioration of performance, attention and motivation; diminishment of mental concentration and intellectual capacity and increase of the likelihood of accidents at work and during driving) and mental health complications.

Chronic insomnia is defined as a complaint of persistent difficulty falling asleep, maintaining sleep, and/or experiencing non-restorative sleep accompanied by significant dysfunction in next-day cognitive, physical, or social functioning.

Chronic insomnia affects approximately 10% of the population with approximately 45% of patients remaining symptomatic after 10 years.¹

OUR SLEEP NEEDS WITH AGE:

1. Sleep; 31 (1); 79-90: 2008

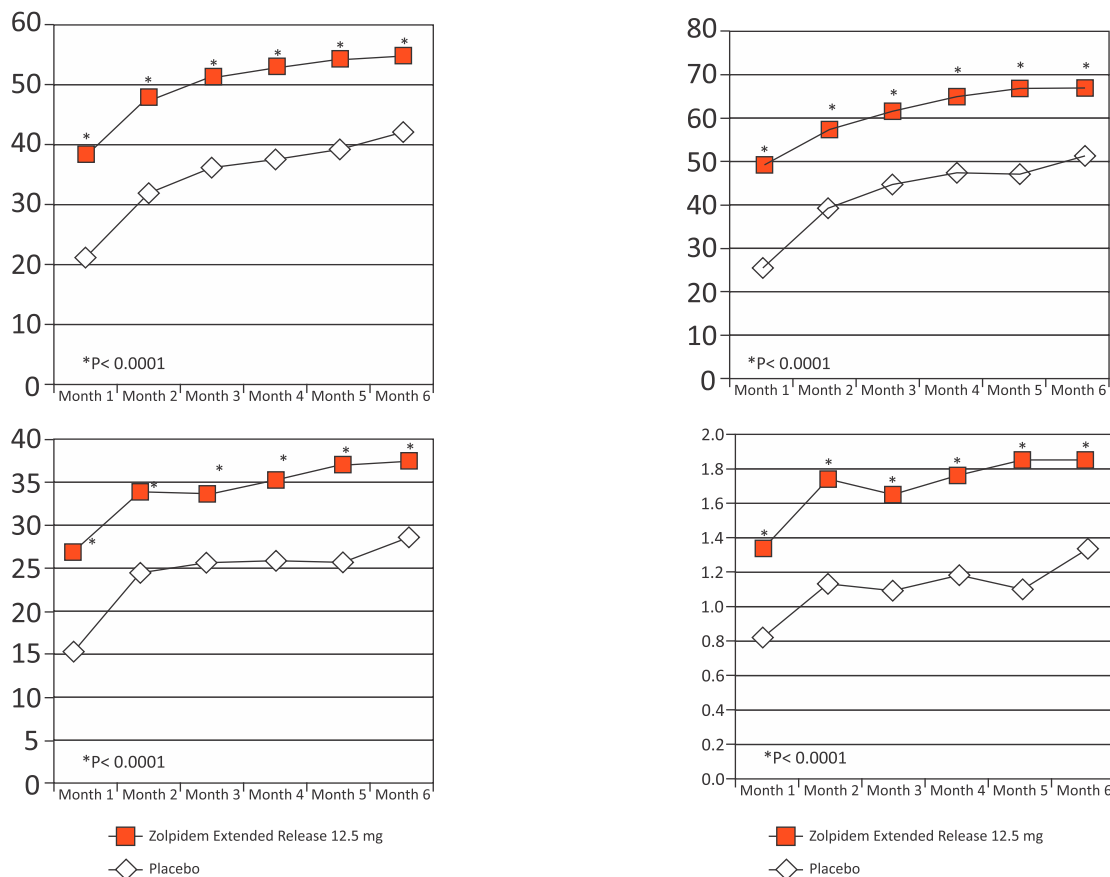
Age	Recommended	May Be Appropriate	Not Recommended
Newborns	14 to 17 hours	11 to 13 hours	Less than 11 hours
0-3 months		18 to 19 hours	More than 19 hours
Infants	12 to 15 hours	10 to 11 hours	Less than 10 hours
4-11 months		16 to 18 hours	More than 18 hours
Toddlers	11 to 14 hours	9 to 10 hours	Less than 9 hours
1-2 years		15 to 16 hours	More than 16 hours
Preschoolers	9 to 11 hours	7 to 8 hours	Less than 7 hours
3-5 years		12 hours	More than 12 hours
Teenagers	8 to 10 hours	7 hours	Less than 7 hours
14-17 years		11 hours	More than 11 hours
Young Adults	7 to 9 hours	6 hours	Less than 6 hours
18-25 years		10 to 11 hours	More than 11 hours
Adults	7 to 9 hours	6 hours	Less than 6 hours
26-64 years		10 hours	More than 10 hours
Older Adults	7 to 8 hours	5-6 hours	Less than 5 hours
≥ 65 years		9 hours	More than 9 hours

CLINICAL EFFECTIVENESS:

- Long-Term Efficacy and Safety of Zolpidem Extended-Release 12.5 mg, administered 3 to 7 Nights per week for 24 weeks, in patients with Chronic Primary Insomnia.
Study on 1048 patients and results were assessed by Patient's Global Impression (PGI) and Clinical Global Impression-Improvement (CGI-I) were assessed every 4 weeks up to week 24.
- Sleep measures assessed by —sleep onset latency (SOL), total sleep time (TST), number of awakenings (NAW), wake time after sleep onset (WASO), and quality of sleep (QOS)—and next day functioning.

RESULTS:

- At week 12, PGI, Item 1 (aid to sleep), the primary endpoint, score was favorable (i.e., "helped me sleep") by 89.8% of zolpidem patients vs. 51.4% of placebo patients ($P < 0.0001$, based on rank score) and at week 24 by 92.3% of zolpidem extended-release patients vs. 59.7% of placebo patients.
- Zolpidem extended-release also statistically significantly superior to placebo at every time point for PGI (Items 1-4) and CGI-I ($P < 0.0001$, rank score), TST, WASO, QOS ($P < 0.0001$), and SOL ($P \leq 0.0014$); NAW (Months 2-6; $P < 0.0001$).
- No rebound effect was observed during the first 3 nights of discontinuation



(Change from baseline in PMQ over 6 months of treatment. For each of the 6 treatment months, patients who received zolpidem extended-release reported significantly greater improvement in TST ($P < 0.0001$), WASO ($P < 0.0001$), and SOL ($P \leq 0.0014$) than did patients who received placebo. Improvement in NAW was also significantly greater at months 2 to 6 in the zolpidem extended-release patients ($P < 0.0001$). NAW = number of nocturnal awakenings; SOL = sleep onset latency; TST = total sleep time; WASO = wake after sleep onset.)

CONCLUSIONS:

Treatment with Zolpidem extended-release 12.5 mg at 3 to 7 nights per week dosing for up to 6 months provides sustained and significant improvements in sleep onset and maintenance and also improved next-day concentration and morning sleepiness.

ZOLPIGRESS

Zolpidem Controlled Release Tablets 12.5 mg

Indication:

ZOLPIGRESS is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.

Composition:

Zolpidem tartrate Controlled Release Tablet 12.5 mg

Mechanism of Action:

- Zolpidemtartrate, is a non-benzodiazepine hypnotic of the imidazopyridine class. It interacts with a GABA- benzodiazepine receptor complex and modulation of the GABAA receptor chloride channel macromolecular complex, responsible for sedative, anticonvulsant, anxiolytic, and myorelaxant drug properties.
- Zolpidem in vitro condition, binds the (BZ1) receptor preferentially with a high affinity ratio of the $\alpha 1/\alpha 5$ subunits. This selective binding of zolpidem on the (BZ1) receptor is not absolute, but it may explain the relative absence of myorelaxant and anticonvulsant effects in animal studies as well as the preservation of deep sleep (stages 3 and 4) in human studies of zolpidem at hypnotic doses.

Dosage:

Dosage: Adult - As controlled release tab: 12.5 mg immediately before bedtime.

Administration:

It should be taken on an empty stomach. Do not take with/ or immediately after a meal.

Advantages:

- Zolpidem-12.5mg control release tablet significantly reduces latency to persistent sleep, and significantly increases sleep efficiency, without next-day residual effects*.
- Residual daytime effects are unlikely with recommended doses. **

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