

# Zolpidem 5 & 10 mg

## Orodispersible tablet



***Orodispersible facilitates oral intake and improves patients' compliance***

## Key features

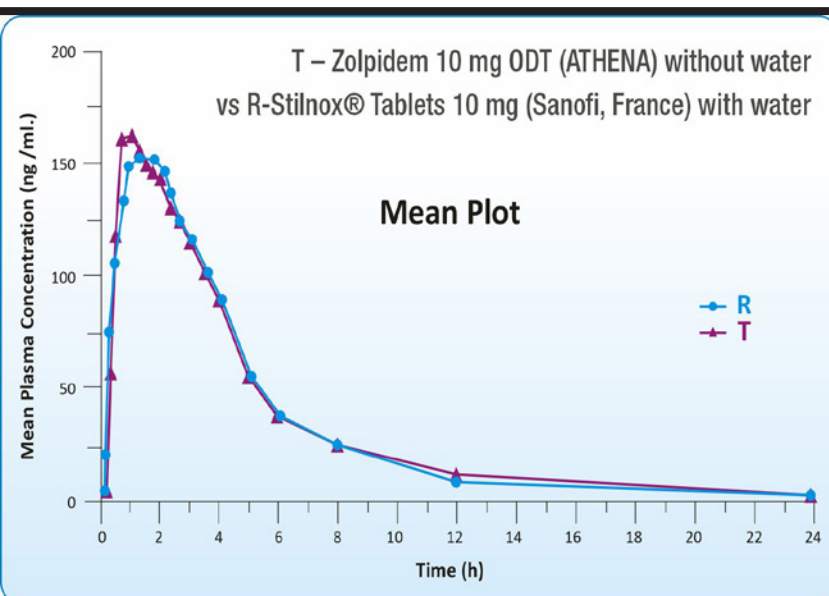
- ODT technology particularly suitable in insomnia patients who have difficulties swallowing tablets, or those who may not, or do not, always have access to water at bedtime<sup>1,2</sup>.

## Competitive advantages

- Zolpidem is particularly suitable for insomniac patient suffering with difficulties with sleep initiation.

## Regulatory status

- INN: Zolpidem hemitartrate
- ATC Code: N05CF02
- CAS registry number: 99294-93-6
- Reference compound: STILNOX<sup>®</sup>, Sanofi.
- BioEq. study
  - Patient population: 38 male & female healthy volunteers.
  - Methodology: 2-way crossover single study (Test w/o water; Reference w/water).
  - Reference product: STILNOX<sup>®</sup>, Sanofi France.
- Zone IV stability.
- CTD dossier available.



## Information at a glance

- Commercial batch size (million doses) / strength: 5 mg: 0.5 | 10 mg: 0.125
- Dossier Batch size (million doses) / strength: 5 & 10 mg: 1
- Shelf-life: 3 years
- Storage conditions: This medicinal product does not require any special storage conditions when packaged in Aluminium-Aluminium blisters.
- Pack info: Alu-Alu 10 tabs-blisters; 10 blister strips / carton
- Tablet weight / strength: 5 mg: 150 mg | 10 mg: 300 mg
- Flavour: Black current

## Market highlights

- Insomnia is one of the largest CNS disorders, affecting on average one adult out of 3<sup>3,4</sup>.
- Global insomnia market valued at \$4.1 billion in 2016 and estimated to reach \$5,5 billion by 2023 at a CAGR of 4.2% from 2017 to 2023<sup>5</sup>.

## Competitors' landscape

- Hypnotic & anxiolytic benzodiazepines (LEXOMIL®/bromazepam, VALIUM®/diazepam, XANAX®/alprazolam) IMOVANE®/zopiclone, LUNESTA®/eszopiclone, SONATA®/zaleplon, sedative anti-H1 (DRAMAMINE®/dimenhydrinate, BENADRYL®/diphenhydramine, DONORMYL®/doxylamine) sedative antidepressants (SINEQUAN®/doxepin, REMERON®/mirtazapine, DESYREL®/trazodone), melatonin receptor agonists (ROZEREM®/ramelteon, BELSOMRA®/survorexant) melatonin & other OTC derivatives.

### REFERENCES

1. Staner L et al Expert Rev. Neurother. 12(2) (2012)
2. Inoue Y et al J Drug Res Dev (1) Vol 3.1 (2017)
3. CDC Newsroom (2016)
4. Roth T J Clin Sleep Med 3(Supp.5)3 S7-S10 (2007)
5. Prescription Sleep Aids and OTC Sleep Aids Allied Market Research (2017)



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## Key numbers

- One adult out of 3 suffer from insomnia
- Global insomnia market valued at \$5.5 billion by 2023
- CAGR 2017-2023: 4.2%

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