

# Donepezil 5 & 10 mg

## OroDispersible Tablet



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

### Key features

- Significant improvement in cognitive and global functions, activity of daily living and in patients suffering from light, moderate or severe Alzheimer's disease after 12-24 weeks of treatment vs. placebo<sup>1,2,3,4,5,6,7,8,9</sup>.
- Clinical improvements in non-cognitive behaviours and in caregiver stress.
- Reduction of the two core symptoms of dementia, i.e. agitation and delusions<sup>10,11,12</sup>.
- Commonly used in Lewy Body dementia and reduce visual hallucinations<sup>13</sup>.

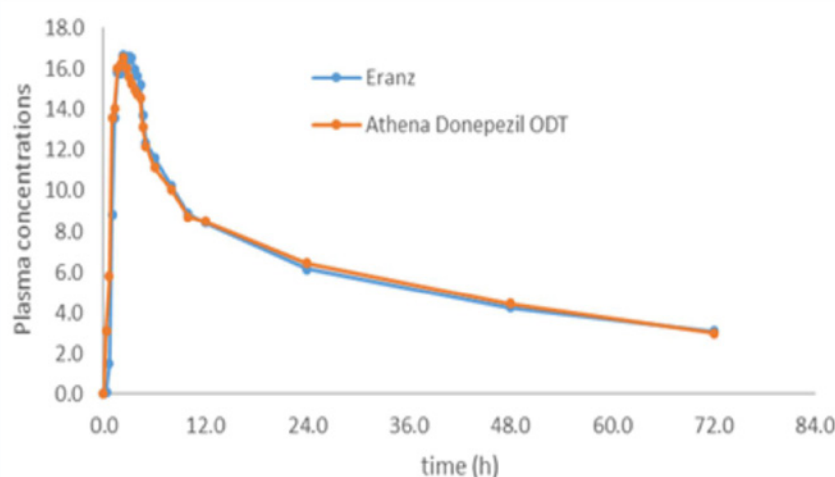
### Competitive advantages

- Lesser behaviour deterioration vs. Galantamine<sup>14</sup>.
- Superior Global Responder Rate vs. Galantamine<sup>14</sup>.
- Lower risk of treatment withdrawals for any reason or because of an adverse event for Donepezil vs. Rivastigmine or Galantamine<sup>14</sup>.

### Regulatory status

- INN: Donepezil
- ATC Code: N06DA02, CAS Registry Number: 120014-06-4
- Reference compound: ARICEPT®, Pfizer.
- BioEq. study
  - Patient population: 40 male & female healthy volunteers.
  - Methodology: Randomized, 3-way cross over study.
  - Reference product: ERANZ®, Wyeth.
- Zone IV stability data available.
- CTD dossier available.

Erantz Vs Athena Donepezil ODT



## Information at a glance

- Commercial batch size / strength (million doses): 5 mg:0.5 | 10 mg: 0.25
- Dossier Batch size / strength (million doses): 5 mg:0.5 | 10 mg: 0.25
- Shelf-life: 2 years
- Storage conditions: Room temperature between 20 and 25°C
- Pack info / strength: Aluminium10-tabs blister and pack
- Tablet weight / strength: 5 mg: 140 mg | 10 mg: 280 mg
- Flavour: Orange

## Market highlights

- According to the WHO, Alzheimer Disease afflicts at least 50 million people throughout the world.
- Alzheimer's Therapeutic Market is expected to reach \$12.4 billion by 2026 (4.6% CAGR 2018-26)<sup>15</sup>.

## Competitors' landscape

- Cholinesterase inhibitors (REMINYL®/galantamine, EXELON®/rivastigmine and COGNEX®/tacrine), NMDA receptor antagonists (NAMENDA®/N-Methyl-D-Aspartate; EBIXA®/Memantine)

### REFERENCES

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## Key numbers

- 50 million peoples suffering from Alzheimer worldwide
- Alzheimer market expected to reach \$12.4 billion by 2026
- CAGR 2018-26: +4.6%

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