

Etifoxine 50 mg

Capsules



Non-benzodiazepine anxiolytic medication with minimal abuse and misuse potential vs. benzodiazepine drugs.

Key features

- Non-benzodiazepine anxiolytic medication indicated in the management of trauma and stress-related disorders associated with anxiety, a highly prevalent disorder^{1,2,3} with a significant impact of the day-to-day function, quality of life of patients and potentially progressing to a more serious disorder⁴.

Competitive advantages

- Anxiolytic effect equivalent to lorazepam, a higher responder rate, and a lower rate of rebound anxiety at treatment discontinuation (one week) in patients receiving etifoxine⁵.

Regulatory status

- INN: Etifoxine
- ATC: N05BX03
- CAS registry number: 56776-32-0
- Reference compound: STRESAM®, Biocodex
- BioEq. Study referenced EIN-P3-750
 - Patient population: 40 fasting healthy volunteers.
 - Methodology: Monocentric randomized blinded single dose 2-periods, 2-sequences crossover
- Zone IVb Stability data: starting in Q2 2021.
- eCTD dossier.

Figure 1: Linear Profile of the Mean for Etifoxine, EIN-P3-750

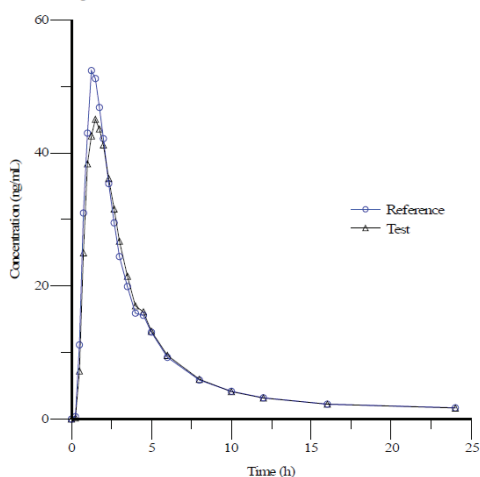
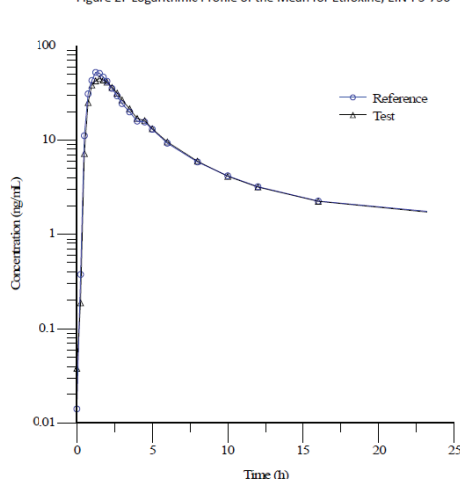


Figure 2: Logarithmic Profile of the Mean for Etifoxine, EIN-P3-750



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Information at a glance

- Commercial Batch size (million doses): 1.0
- Dossier Batch size (million doses): 1.0
- Shelf-life: 3 years
- Storage conditions: Do not store above 25°C.
- Pack info: PVC (250 µm)/PVDC (90g/m²) Alu. (25 µm) blister pack of 15 capsules (box of 60 capsules)
- Capsule weight: 263 mg

Market highlights

- Adjustment disorder has been reported to be almost three times as common as major depression (13.7% vs. 5.1%) in acutely ill medical in-patients⁶
- The Global anxiety disorder and depression treatment market is forecasted to reach \$18.9 Bi by 2026 (CAGR of 2.4%)⁷
- Anxiety disorder treatment market is expected to reach \$16.7 M at a CAGR of 5.4% by 2025⁸.

Competitors' landscape

- Anxiolytic benzodiazepines (XANAX®/alprazolam, VALIUM®/diazepam, TEMESTA®/lorazepam, LEXOMIL®/bromazepam), buspirone, and ATARAX®/hydroxyzine.

REFERENCES

1. Glaesmer H et al *Psychiatry res* (2015)
2. Perkonig A et al *Clin. Health Psychol.* (2018)
3. Killikelly C et al *Affect. Disord.* (2019)
4. O'Donnell M.L. *Am. J. Psychiatry* (2016)
5. Nguyen N et al *Hum Psychopharmacol* (2006)
6. Silverstone PH J. *Nerv Ment Dis* (1996)
7. *Anxiety and Depression Treatment market by Therapies, Reports and Date* (2020)
8. *Global Anxiety Disorder Treatment Market Research by Market Research Future* (2021)



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Key numbers

- Anxiety disorder treatment market expected to reach \$16,7 M by 2025

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