

Levocetirizine 5 mg

Orodispersible tablet



Orodispersible facilitates oral intake and improves patients' compliance

Key features

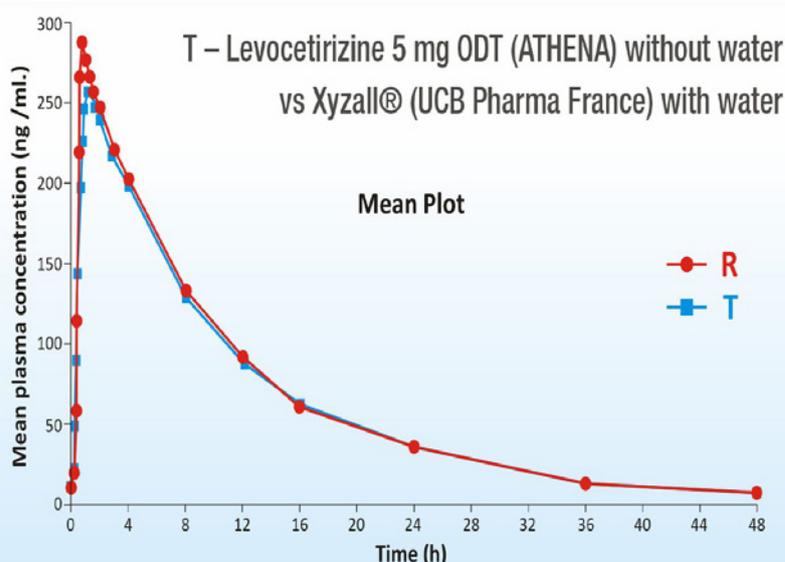
- Second-generation piperazine derivative with potent H1-selective antihistaminic activity.
- Improved oral bioavailability and onset of action vs. conventional oral slide form by avoiding hepatic first-pass effect.
- Nasal decongestant effect, in contrast to older conventional anti-histaminic agents^{1,2}.

Competitive advantages

- Levocetirizine efficacy superior to loratadine, desloratadine and fexofenadine^{3,4,5,6,7,8}.
- 43% saving on the social cost of persistent allergic rhinitis⁹.
- Minimal impairment of memory and psychomotor functioning nor mood changes after acute and sub chronic administration of levocetirizine¹⁰.

Regulatory status

- INN: Levocetirizine
- ATC Code: R06AE09
- CAS registry number: 0130018-77-8
- Reference compound: XYZALL[®], UCB Pharma.
- BioEq. study
 - Patient population: 23 male and female healthy volunteers.
 - Methodology: Randomized, single-dose 2-way crossover study (test without water vs. Reference with water).
 - Reference product: XYZALL[®], UCB Pharma France.
- Zone IV stability data available.
- CTD dossier available.



Levocetirizine 5 mg

Orodispersible tablet

ALLERGY

Information at a glance

- Commercial batch size (million doses): 0.5
- Dossier Batch size (million doses): 0.125
- Shelf-life: 3 years
- Storage conditions: Room temperature between 20-25°C
- Pack info: Alu-Alu 10-tabs blister
- Tablet weight / strength: 250 mg
- Flavour: Blackcurrant

Market highlights

- Allergic rhinitis affects around 10 to 30% of the population every year¹¹.
- The global antihistamine market is projected to reach \$277 million by 2026 at a CAGR of 5.6% from 2021 to 2026¹².
- Second-generation antihistamines segment is the largest market¹³.

Competitors' landscape

- First-generation (non-selective) antihistaminic drugs (BENADRIL[®]/diphenhydramine, RYVENT[®]/carbinoxamine), second-generation (selective) antihistaminic drugs (ZYRTEC[®]/cetirizine, CLARITIN[®]/loratadine, AERIUS[®]/ebastine, TELDANE[®]/terfenadine) and third-generation antihistaminic drugs (CLARINEX[®]/desloratadine, ALLEGRA[®]/fexofenadine).

REFERENCES

1. Nettis E et al J Asthma Allergy 2:17-23 (2009)
2. Gandhi GS et al J Appl Pharm Sci 1:145-150 (2011)
3. Horak F et al Allergy 56(Suppl 68):201-202 (2001)
4. Passamacqua G et al Int Arch Allergy Clin Immunol 135:143-147 (2004)
5. Deruaz C et al J Allergy Clin Immunol 114:838-844 (2004)
6. Ciprandi G et al Clin Exp Allergy 34:958-964 (2004)
7. Day JH et al Int J Clin Pract 58:109-118 (2004)
8. Horak F et al Br J Clin Pharmacol 60:24-31 (2005)
9. Bousquet J et al Allergy 60:788-794 (2005)
10. Verster J et al J Allergy Clin Immunol 111:623-627 (2003)
11. American Academy of Allergy Asthma & Immunology (AAAAI)
12. Global antihistamine drugs market research report, QYResearch (2020)
13. Global antihistamine market 2018-2026, Research and Markets (2018)



Disclaimer: Athena if performed, will make available to potential customers its own IP assessment. Potential customers may on the basis thereof make their own independent assessment with respect to the absence of the violation of any intellectual property rights of any third party in the development and use of the regulatory dossier that could render unlawful the manufacture, import, marketing, sale, and/or distribution of the products in the relevant territory.

Key numbers

- Allergic rhinitis affects 10% to 30% of the population every year
- Global anti-histaminic market: \$277 million by 2026
- CAGR 2021-26: 5.6%

ASIA patil.amit@ddsathena.com

CANADA/USA hafid@tradepassrx.com

FRANCE francois.ribeaux@athenaips.com

GLOBAL hugues.benevent@athenaips.com
frederic.besancon@athenaips.com
awilliams@ddsathena.com

LATAM schauenberg.bruno@ddsathena.com

MENA patil.amit@ddsathena.com

OTHER contact@ddsathena.com