

Bilastine 10 mg & 20 mg

Oro-Dispersible Tablet



A unique effective antihistamine without sedation

Key features

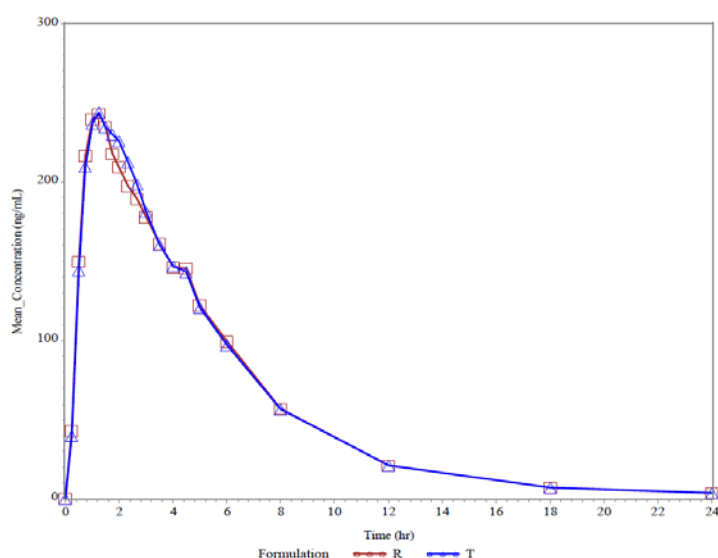
- Bilastine is a non-sedating oral highly selective H₁-receptor antagonist, indicated to treat the symptoms of allergic disorders (e.g. rhinoconjunctivitis and urticaria) in adults and adolescents and, more recently, in children.¹
- Bilastine epitomizes the evolution of research on antihistamines concerning both efficacy and safety. Efficacy of Bilastine was well recognized in both seasonal and perennial allergic rhinitis³.
- It is an anti-allergic agent whose main mechanism of action is the inhibition of immune system reactions mediated by the interaction of histamine on its H₁- receptor² with a high affinity for histamine H₁ receptors, 3 times more effective than cetirizine and 5 times of fexofenadine².

Competitive advantages

- Bilastine is a potent, effective antihistamine, without sedation, without cardiac toxicity, it has absence of metabolism and does not interact with cytochrome P4502.
- In experimental models, Bilastine has shown an excellent dose-dependent activity when administered by oral or intravenous route always higher than that of fexofenadine and, in certain models, also higher than that of Cetirizine²
- The long duration of action, efficacy, low-sedation impact and low-performance impairment of second generation antihistamines, and particularly of Bilastine, make it a potentially attractive therapeutic option for allergists.

Regulatory status

- INN: Bilastine
- CAS registry number: 202189-78-4
- ATC code: S01GX13
- Zone IVb stability: Available
- Bioequivalence Study: Available
- Patient population: 40 (34 male , 6 female)
- Methodology: Two way crossover fasting pivotal study
- Reference product: Bilaska[®] 20mg Tablet, Faes Marketed in France
- e-CTD dossier : Available



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ALLERGY

Information at a glance

- Commercial batch size: 10 mg: 500 000 Tablets | 20 mg: 250 000 Tablets
- Dossier Batch size: 10 mg: 500 000 Tablets | 20 mg: 250 000 Tablets
- Shelf-life: 3 years
- Storage conditions: Store at room temperature up to 25°C
- Pack Info: Alu-Alu Blister Pack of 10 Tablets
- Tablet weight / strength: 10 mg Tablet weight- 80 mg \pm 7.5 % | 20 mg Tablet weight: 160 mg \pm 5%

Market highlights

- The Global Bilastine market is anticipated to rise at a considerable rate during the forecast period, between 2022 and 2028. In 2021, the market is growing at a steady rate and with the rising adoption of strategies by key players, the market is expected to rise over the projected horizon.⁵
- The long duration of action, efficacy, low-sedation impact and low-performance impairment of second generation antihistamines, and particularly of bilastine, make it a potentially attractive therapeutic option for allergists.

Competitors' landscape

- The global key manufacturers of Bilastine include Aralez Pharmaceuticals, Takeda, Menarini, Taiho Yakuhin, Faes Farma, Berlin Chemie, GlaxoSmithKline and Pierre Fabre, etc.

REFERENCES

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Key numbers

- The Global Bilastine market is anticipated to rise at a considerable rate during the forecast period, between 2022 and 2028.
- In 2021, the market is growing at a steady rate and with the rising adoption of strategies by key players, the market is expected to rise over the projected horizon

ASIA matthews.bernadette@ddsathena.com

AFRICA khan.fateh@ddsathena.com

CANADA/USA hafid@tradepassrx.com

GLOBAL hugues.benevent@athenaips.com
frederic.besancon@athenaips.com
patil.amit@ddsathena.com
mayte.mayo@athenaips.com

LATAM schauenberg.bruno@ddsathena.com

MENA patil.amit@ddsathena.com

OTHER contact@ddsathena.com