EXPERIENCE COMPLETE
ALLERGY PROTECTION[1-4]

Alicia*, 28-year old entrepreneur

Suffers from ALLERGIC RHINOCONJUCTIVITIS for 2 years

Wants fast, effective and long-lasting relief from her bothersome symptoms in order to start off her day right.

* Hypothetical patient profile

BILAXTEN®
bilastine 20 mg

BILAXTEN® scored the HIGHEST number of desired features for a second-generation antihistamine according to ARIA GUIDELINES[5,a]

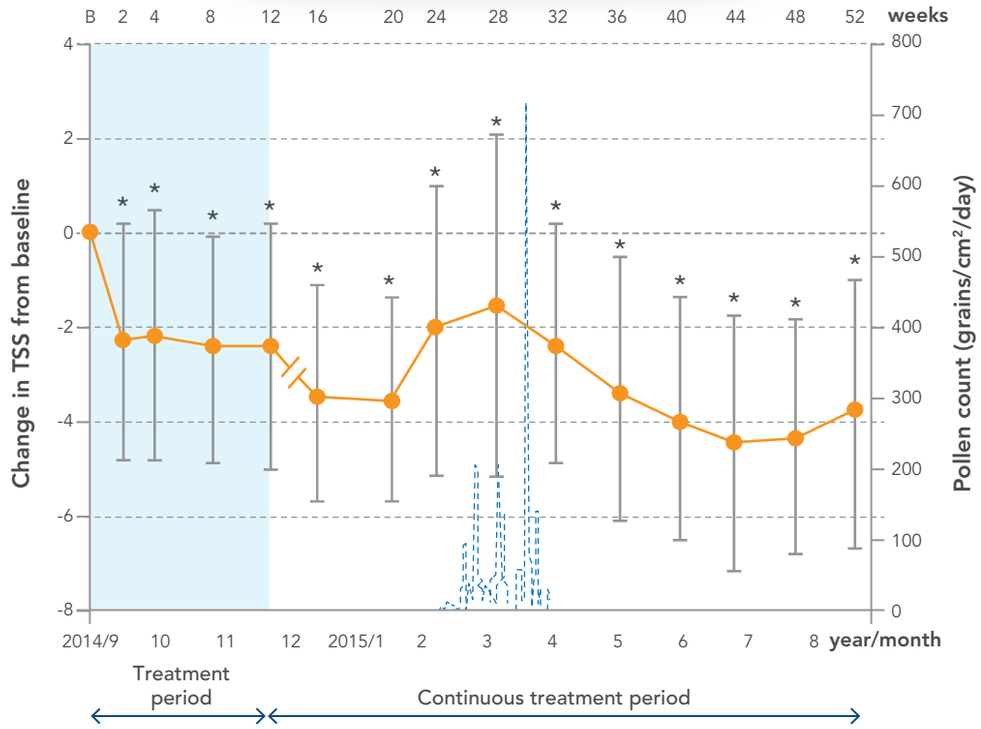
Requirements of the ideal oral H1- antihistamine[7,b,c]	BILAXTEN® bilastine 20 mg
Potent and selective H1-blockade[5]	✓
Rapid onset of action[2]	✓
Long duration of action[2]	✓
Effective in both intermittent and persistent allergic rhinitis[5]	✓
Effective against all nasal symptoms, including obstruction[5]	✓
Improves ocular symptoms[5]	✓
No sedation[6]	✓
No anticholinergic activity[6]	✓
No interaction with cytochrome P450[6]	✓
No cardiac safety concern[5]	✓

ARIA 10 SCORE

a Compared with fexofenadine, cetirizine, desloratadine, ebastine, levocetirizine and loratadine.
b Adapted from Bousquet J, Khaltaev N, Cruz AA, et al; World Health Organization; GA(2)LEN; AllerGen. Allergic rhinitis and its impact on asthma (ARIA) 2008 update (in collaboration with the World Health Organization, GA(2)LEN and AllerGen). Allergy. 2008;63(suppl 86):8–160.
c These are not the only properties an antihistamine should have, according to ARIA guidelines. These are those properties, among all that included in the list of requirements from Table 1 of ARIA guidelines [5] that bilastine has.

BILAXTEN® is EFFECTIVE AND WELL-TOLERATED IN LONG-TERM treatment of allergic rhinitis[3]

Mean change in TSS from baseline through the 52 weeks treatment[3]



*p < 0.01 vs baseline

Adapted from Okubo et al. 2017[3]

Prolonged treatment with **Bilaxten®** resulted in maintenance of a **significant reduction** in TSS from baseline in patients with PAR during the **52-week treatment period**.[3]

No suggesting patients withdrew from the study because of adverse events (AEs) suggested that **Bilaxten®** has **good tolerability profile**.[3]

Open-label, single-arm, phase III study evaluating the efficacy and safety of long-term treatment with bilastine in Japanese patients with seasonal (SAR) and perennial allergic rhinitis (PAR). Safety and tolerability were the primary outcomes, and the main secondary endpoint was to evaluate changes in efficacy variables from baseline measurements. Graph shows change in scores from baseline during the 52 weeks (w) in PAR, and pollen counts (Japanese cedar + cypress pollen) during the 2015 cedar pollen scattering season in Osaka. Each value represents mean ±SD (number of patients; baseline: n = 64, 2 w, 4 w, 8 w: n = 63, 12 w: n = 62, 16 w, 20 w: n = 55, 24 w: n = 54, 28 w, 36 w, 40 w, 44 w: n = 53, 32 w, 48 w, 52 w: n = 52). Pollen count (dashed-line) data were obtained from the Ibaraki Public Health Center (Osaka, Japan).

TSS: Total symptom scores; PAR : Perennial allergic rhinitis

A PROVEN COMBINATION OF HIGH EFFICACY WITH A GOOD TOLERABILITY PROFILE

BILAXTEN®
bilastine 20 mg

- Fast action and long-lasting allergy protection beyond 24 hours[2,8]
- Excellent symptom relief for allergic rhinoconjunctivitis and urticaria[2-4]
- Non-sedating and non-brain-penetrating antihistamine[8,9]
- Well-tolerated in long-term allergy treatment and no dose adjustments* needed[1,3,4]

* For renal impairment, hepatic impairment and elderly patients

^ A crossover, randomized, double-blind, placebo-controlled clinical study. Subjects received single doses of bilastine 20 mg, desloratadine 5mg, rupatadine 10mg and placebo. Wheal (W) & Flare (F) responses induced by intradermal injection of histamine 5 µg were evaluated before treatment (basal value) and at 0.5-24 hours after treatment. The primary outcome measure was the percentage reduction in W&F areas after each active treatment compared with corresponding basal values.[7]

References: 1. Bilaxten® Local SmPC Package Insert. **2.** Horak F et al. The effects of bilastine compared with cetirizine, fexofenadine, and placebo on allergen-induced nasal and ocular symptoms in patients exposed to aeroallergen in the Vienna Challenge Chamber. Inflamm Res. 2010; 59(5): 391–398. **3.** Okubo K et al. Long-term safety and efficacy of bilastine following up to 12 weeks or 52 weeks of treatment in Japanese patients with allergic rhinitis: Results of an open-label trial. Auris Nasis Larynx 2017;44(3):294-301. **4.** Yagami A et al. Japanese patients with chronic spontaneous urticaria or pruritus associated with skin diseases. Journal of Dermatology 2017; 44: 375–385. **5.** Wang XY et al. Treatment of allergic rhinitis and urticaria: a review of the newest antihistamine drug bilastine. Ther Clin Risk Manage 2016;12:585–597. **6.** Jauregui I. et al. Bilastine: a new antihistamine with an optimal benefit-to-risk ratio for safety during driving. Expert Opin. Drug Saf. (2015) 15(1). **7.** Boustead et al. Allergic Rhinitis and its Impact on Asthma (ARIA) 2008 update (in collaboration with the World Health Organization, GA(2)LEN and AllerGen). Allergy 2008;63:8–160. **8.** Antonijoan R et al. Comparative efficacy of bilastine, desloratadine and rupatadine in the suppression of wheal and flare response induced by intradermal histamine in healthy volunteers.Curr Med Res Opin. 2017;33:129-36 **9.** Kawauchi H et al. Antihistamines for Allergic Rhinitis Treatment from the Viewpoint of Nonsedative Properties. Int J Mol Sci. 2019;20(1). pii: E213.

Abbreviated Prescribing Information[1]

BILAXTEN® tablet 20 mg. THERAPEUTIC INDICATIONS: Symptomatic treatment of allergic rhino-conjunctivitis (seasonal and perennial) and urticaria. **POSOLOGY AND METHOD OF ADMISTRATION:** Adults and adolescents (12 years of age and over) 20 mg (1 tablet) once daily for the relief of symptoms. The tablet should be taken by oral route one hour before or two hours after intake of food or fruit juice. CONTRAINDICATIONS: Hypersensitivity to the active substance (bilastine) or to any of the excipients. **PRECAUTIONS:** Efficacy and safety of Bilastine in children under 12 years of age have not been established. **In patients with moderate or severe renal impairment co-administration of bilastine with P-glycoprotein inhibitors, such as ketoconazole, erythromycin, cyclosporine, ritonavir or diltiazem, may increase plasmatic levels of bilastine and therefore increase the risk of adverse reactions of bilastine. Therefore, co-administration of Bilastine and P-glycoprotein inhibitors should be avoided in patients with moderate or severe renal impairment.** Food significantly reduces the oral bioavailability of bilastine by 30% concomitant intake of bilastine 20 mg and grapefruit juice decreased bilastine bioavailability by 30%. This effect may also apply to other fruit juices. Concomitant intake of bilastine and ketoconazole or erythromycin increased bilastine AUC 2-fold and Cmax 2-3 fold. Concomitant intake of bilastine 20 mg and diltiazem 60 mg increased Cmax of bilastine by 50%. A study performed to assess the effects of bilastine on the ability to drive demonstrated that treatment with 20 mg did not affect the driving performance. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines **FERTILITY, PREGNANCY AND LACTATON:** Fertility: There are no or limited amount of clinical data. Pregnancy: There are no or limited amount of data from the use of bilastine in pregnant women. As a precautionary measure, it is preferable to avoid the use of bilastine during pregnancy. Breast-feeding: It is unknown whether bilastine is excreted in human breast milk. A decision on whether to discontinue/abstain from bilastine therapy must be made taking into account the benefit of breast-feeding for the child and the benefit of bilastine therapy for the mother. **UNDESIRABLE EFFECTS:** The incidence of adverse events in patients suffering from allergic rhino-conjunctivitis or chronic idiopathic urticaria treated with 20 mg bilastine in clinical trials was comparable with the incidence in patients receiving placebo. The ADRs most commonly reported by patients receiving 20 mg bilastine were headache, somnolence, dizziness, and fatigue. These adverse events occurred with a comparable frequency in patients receiving placebo.

Please refer to the prescribing information before prescribing. Full pescribing information available upon request.

For Medical and Healthcare Professionals only.

MENARINI

A. Menarini Singapore Pte. Ltd. (994247-T)
B-18-2, Level 18 ,The Ascent Paradigm, No 1, Jalan SS7/26A, Kelana Jaya,
47301 Petaling Jaya, Selangor Darul Ehsan, Malaysia.
Tel: +603 7985 7000/7100 | Fax: +603 7955 3530 | www.menariniapac.com

MY-BIL-201907-001