BILAXTEN®

bilastine 20 mg

Win the battle against allergies

A novel **non-sedating H_1 antihistamine** effective for the symptomatic treatment of allergic rhinoconjunctivitis and urticaria[1]

- **Rapid relief** and **long duration** of action (beyond 24 hours)[2]
- **Effective relief** of allergic rhinitis, allergic rhinoconjuctivitis and all types of urticaria[3,4,5]
- Good **safety and tolerability** profile[3,4,5,6]
- **No dose adjustment** needed and convenient prescribe[7,8,9]
- **Once daily** dosing[7]

References: 1. Bousquet J, Ansótegui I, Canonica GW, Zuberbier T, Baena-Cagnani CE, Bachert C et al. Establishing the place in therapy of bilastine in the treatment of allergic rhinitis according to ARIA: evidence review. *Curr Med Res Opin.* 2011; 28(1):131-139. **2.** Horak F, Zieglmayer P, Zieglmayer R and Lemell P. 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.** Bachert C, Kuna P, Sanquer F, Ivan P, Dimitrov V, Gorina MM et al. Comparison of the efficacy and safety of bilastine 20 mg vs desloratadine 5 mg in seasonal allergic rhinitis patients. *Allergy.* 2009; 64(1):158-165. **4.** Kuna P, Bachert C, Nowackiz Z, Cauwenbergew P, Agache I, Fouquertz L et.al. Efficacy and safety of bilastine 20 mg compared with cetirizine 10 mg and placebo for the symptomatic treatment of seasonal allergic rhinitis: a randomized, double-blind, parallel-group study. *Clin Exp Allergy.* 2009; 39(9):1338-1347. **5.** Zuberbier T, Aberer W, Asero R, Bindslev-Jensen C, Brzoza Z and Canonica GW. The EAACI/GA2 LEN/EDF/WAO Guideline for the definition, classification, diagnosis, and management of urticaria: the 2013 revision and update. *Allergy.* 2014; 69(7):868-887. **6.** Farré M, Pérez-Mañá C, Papaseit E, Menoyo E, Pérez M, Martin S et al. Bilastine vs. hydroxyzine: occupation of brain histamine H1 -receptors evaluated by positron emission tomography in healthy volunteers. *Br J Clin Pharmacol.* 2014; 78(5):970-980. **7.** Bilaxten® Package Insert. **8.** Tyl B, Kabbaj M, Azzam S, Sologuren A, Valiente R, Reinbolt E et al. Lack of significant effect of bilastine administered at therapeutic and supratherapeutic doses and concomitantly with ketoconazole on ventricular repolarization: results of a thorough QT study (QTQS) with QT-concentration analysis. *J Clin Pharmacol.* 2012; 52(6):893-903. **9.** Church MK. Safety and efficacy of bilastine: a new H1-antihistamine for the treatment of allergic rhinoconjunctivitis and urticaria. *Expert Opin Drug Saf.* 2011; 10(5):779-793.

For Medical and Healthcare Professionals only

For further information consult full prescribing information

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MY/BIX/03/2017/0010

BILAXTEN®

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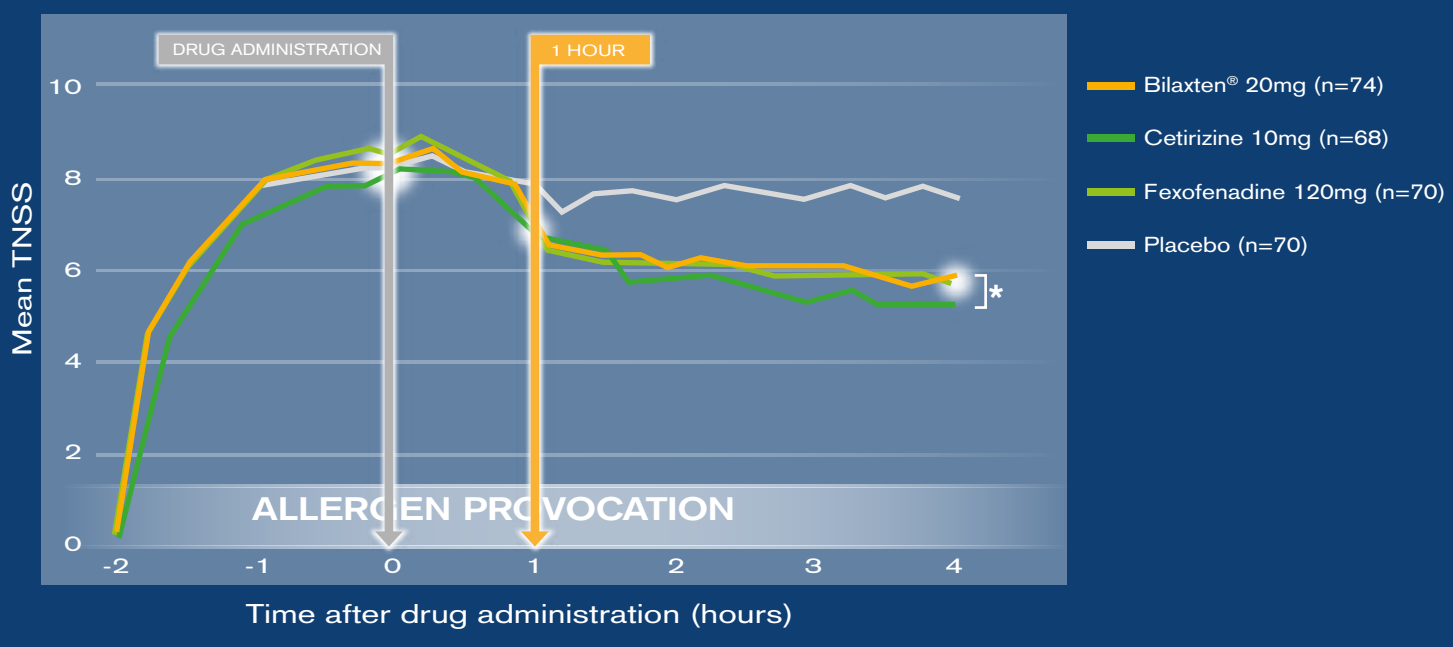
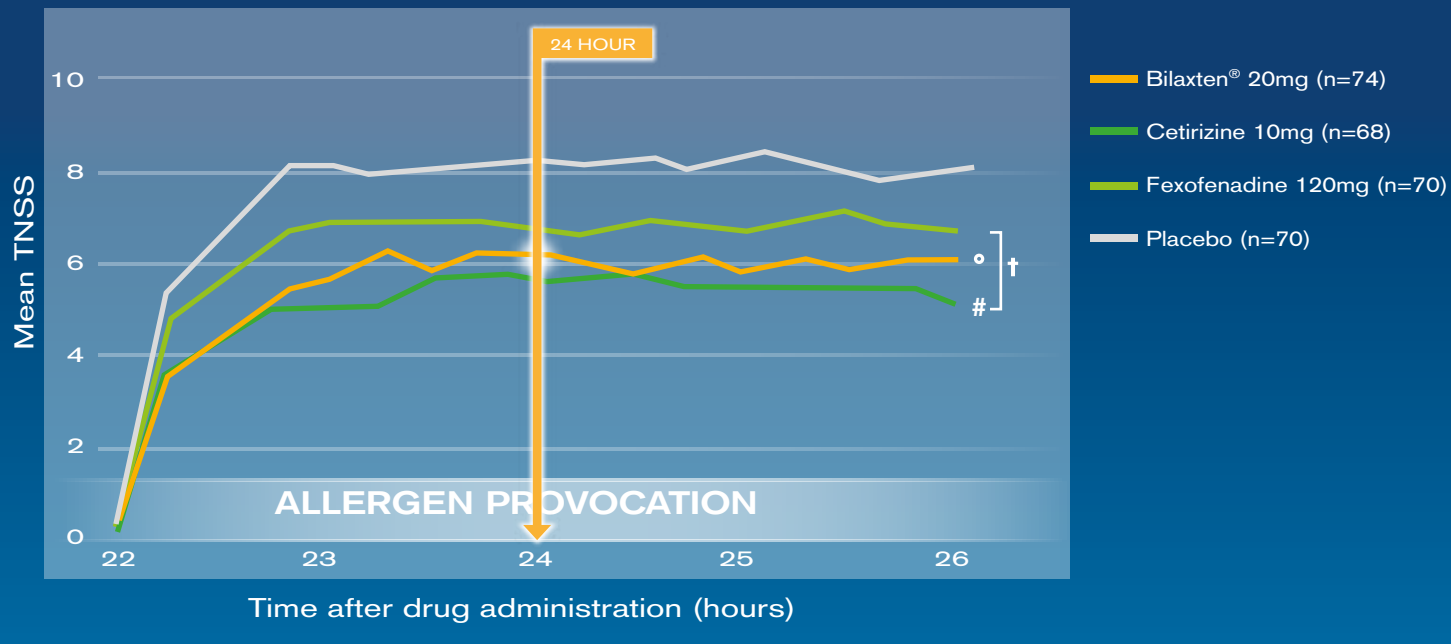
Win the battle against allergies

Rapid onset of action and durable efficacy

BILAXTEN® : Rapid relief within 1 hour[1]



BILAXTEN® : Lasts beyond 24 hours[1]



*p < 0.001 for Bilaxten®, cetirizine and fexofenadine vs placebo
†p < 0.001 for Bilaxten®, cetirizine and fexofenadine vs placebo
#p< 0.001 for cetirizine vs fexofenadine
°p < 0.0012 for Bilaxten® vs fexofenadine

The time course of the effects of Bilaxten® 20 mg (n = 74), cetirizine 10 mg (n = 68), fexofenadine 120 mg (n = 70), and placebo (n = 70) plotted against the allergen-induced increase in Total Nasal Symptom Score (TNSS; the sum of the four individual symptom scores for sneezing, rhinorrhea, nasal obstruction, and nasal itching) assessed every 15 min in the Vienna Challenge Chamber. Results of a single center, double-blind, randomized, placebo-controlled, balanced fourtreatment, four period crossover phase II study performed outside of the pollen season in individuals with asymptomatic seasonal allergic rhinitis. Adapted from figure 1 of reference 1.

Reference: 1. Horak F, Zieglmayer P, Zieglmayer R and Lemell P. 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.

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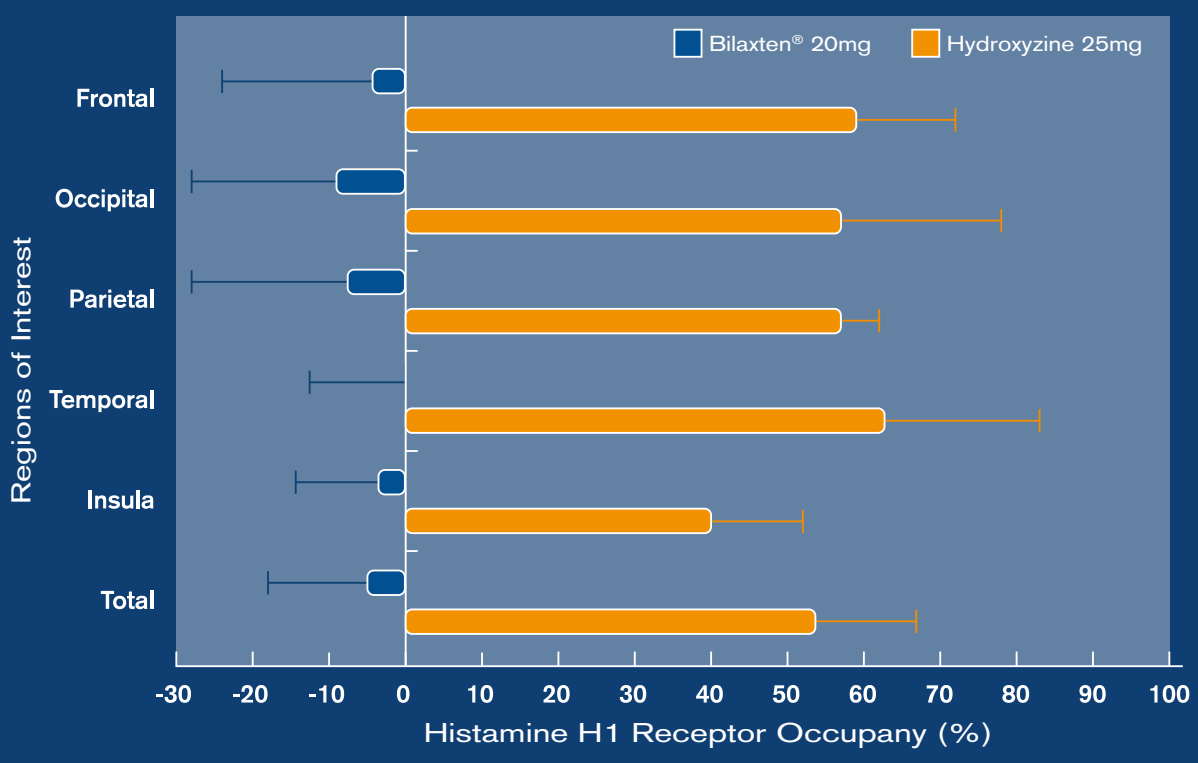
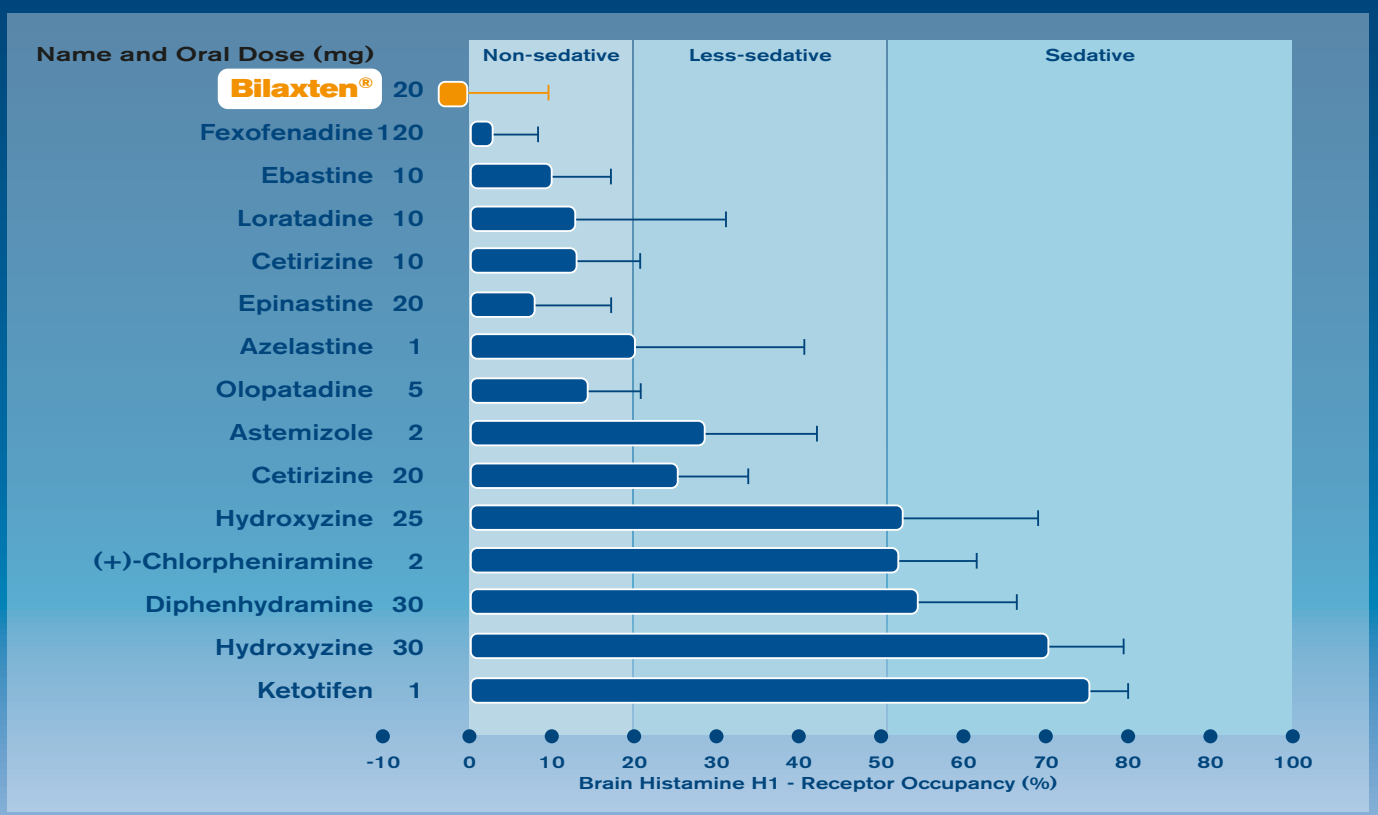
Limited penetration of blood-brain barrier

BILAXTEN® : Occupancy of H_1 receptor is close to zero (-3.92)[1]



BILAXTEN® is the least sedating among 2nd Generation AHs[2]



Mean Receptor Occupancy (RO, ±SD) at each of the five Regions of Interest (ROIs)

$$RO = \frac{BP\ (placebo) - BP\ at\ T_{max}\ (drug)}{BP\ (placebo)} \times 100$$

BP = binding potential

Binding potential is determined by graphical processing of time-activity curves derived from the dynamic Positron Emission Tomography (PET) data.

*AHs: Antihistamines

References: 1. Farré M, Pérez-Mañá C, Papaseit E, Menoyo E, Pérez M, Martin S et al. Bilastine vs. hydroxyzine: occupation of brain histamine H1 -receptors evaluated by positron emission tomography in healthy volunteers. Br J Clin Pharmacol. 2014; 78(5):970-980. **2.** Yanai K and Tashiro M. The physiological and pathophysiological roles of neuronal histamine: an insight from human positron emission tomography studies. Pharmacol Ther. 2007; 113(1):1-15.

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