# A LIFE FREE OF SYMPTOMS


**BILASTINE**

Scored tablet 20 mg

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Scored tablet 20 mg

## APPROVAL PATH

EMA 2010 | Health Canada 2016 | Pmda 2016 | TGA CERTIFIED 2021

Now used **in over 120 countries**

***Mechanism of action:*** *A second generation, inverse agonist of H1 receptor*
***Effective on:*** *Seasonal and perennial allergic rhinitis, Chronic spontaneous urticaria*

## CLINICAL TRIALS

### Seasonal Allergic Rhinitis

Double blind | randomized | multicenter | Placebo & active controlled | N: 721

*TSS: total symptom score*
*RQLQ: rhinoconjunctivitis quality of life questionnaire*

| | Bilastine | Desloratadine | Placebo | |
|---|---|---|---|---|
| *TSS change from baseline on day 14:* | -48.9 | -49.5 | -37.4 | P value 0.001 for bilastine vs. placebo |
| *RQLQ* | -1.6 | -1.6 | -1.3 | P value 0.005 for bilastine vs. placebo |

*Significantly decreased total symptom score and improved quality of life in bilastine group vs. placebo group*

### Seasonal Allergic Rhinitis

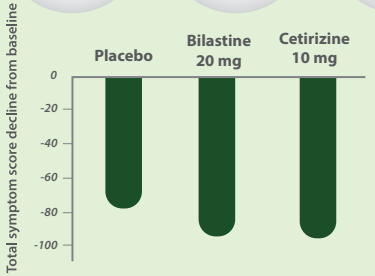
Double blind | randomized | multicenter | Placebo & active controlled | N: 681

| | Bilastine | Cetirizine | Placebo | |
|---|---|---|---|---|
| *TSS change from baseline on day 14:* | -4.76 | -5.32 | -2.88 | Pvalue <0.001; bilastine vs. placebo |
| *Adverse effect (somnolence and fatigue)* | 14.5% | 24.6% | 19.5% | Pvalue <0.05; bilastine vs. placebo<br>Pvalue <0.01; bilastine vs. cetirizine |

*Significantly decreased total symptom score for bilastine vs. placebo and less adverse effect in bilastine group vs. cetirizine group*

## Perennial Allergic Rhinitis

Double blind | randomized | multicenter | Placebo & active controlled | N: 650




Europe+Argentina

*significantly decreased total symptom score in Bilastine group compared to placebo, P value < 0.001*

## Chronic Spontaneous Urticaria

Double blind | randomized | multicenter | Placebo & active controlled | N: 304

| | Bilastine | Placebo | |
|---|---|---|---|
| *change in TSS in day 14* | -3.02 | -1.47 | P value <0.001 |
| *Change in Dermatology Life Quality Index* | -6.2 | -4 | P value <0.001 |

*Significantly decreased total symptom score and improved quality of life in bilastine group vs. placebo group*

*Bilastine had significantly lower adverse effects compared to cetirizine, desloratadine and levocetirizine; relative ratio : 0.84, P=0.03*

## CLINICAL STRENGTHS

- No significant adverse effect compared to placebo
- Significant improvement of seasonal and perennial allergic rhinitis as well as urticaria compared to placebo
- **significantly lower sedation, dry mouth, apetite change and etc. because of no affinity for serotonergic, muscarinic, dopaminergic or noradrenergic receptors**
- Significantly improved quality of life compared to placebo
- Safe in hepatic and renal insufficiency
- Safe in elderly

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## PHARMACOKINETIC STRENGTHS


ONCE DAILY


AROUND THE CLOCK RELIEF


FAST ACTING WITHIN 1 HOUR

## SmPC

**INDICATIONS AND USAGE:**
Bilastine is indicated for the symptomatic treatment of Allergic Rhinoconjunctivitis (Allergic Rhinitis- both Seasonal and Perennial ) and/or urticaria

**DOSAGE AND ADMINISTRATION:**

**Allergic Rhinitis and Urticaria - Adults and adolescents (12 -17 years of age)**
Take one Bilastine tablet daily, as required for symptom control according to allergen exposure, symptom severity and expected course of symptoms.
No dosage adjustment is required in renal or hepatic impairment or in the elderly.

**METHOD OF ADMINISTRATION**
Bilastine should be swallowed whole, with a glass of water, at least 1 hour before or 2 hours after intake of food or fruit juice.

**DOSAGE FORMS AND STRENGTHS:**
Each tablet contains 20 mg of Bilastine.

**CONTRAINDICATIONS:**
Hypersensitivity to Bilastine or to any of the excipients.

**WARNINGS AND PRECAUTIONS:**

**Use in hepatic impairment**
No dosage adjustment is required in patients with hepatic impairment; since Bilastine is not metabolized and is eliminated unchanged in urine and faeces. Hepatic impairment is not expected to increase systemic exposure above the safety margin.

**Use in renal impairment**
No dosage adjustment is required in patients with renal impairment. In patients with moderate or severe renal impairment, co-administration of Bilastine with P-glycoprotein inhibitors such as cyclosporine or diltiazem should be approached with caution as elevated Bilastine plasma levels and higher incidence of adverse reactions such as dizziness, headache and nausea may occur.

**Use in the elderly**
No dosage adjustment is required in elderly patients. Data from Phase 2, 3 and post authorisation studies found no difference in efficacy or safety in elderly patients over 65 years of age compared to younger adults.

**Use in Pediatrics**
No difference in efficacy and safety was observed in clinical trials with Bilastine in adolescents 12 to 17 years compared to the adult population.
There is currently no data on the use of Bilastine in children aged 2 years or younger for allergic rhinoconjunctivitis or urticaria. The safety and efficacy of Bilastine in children below 12 years has not yet been established.

**Effects on laboratory tests**
No data available.

**ADVERSE REACTIONS:**
Most common adverse reactions (incidence ≥4%) are headache and drowsiness.

**DRUG INTERACTIONS:**
Concomitant intake of Bilastine and grapefruit juice decreased Bilastine bioavailability by 30%. This effect may also apply to other fruit juices. Please discuss with your doctor if you are receiving any of the following drugs: Ketoconazole, Erythromycin, Diltiazem, Cyclosporine, Ritonavir, and Rifampicin.

**USE IN SPECIFIC POPULATIONS:**

**Pregnancy and lactation**
There are limited data available on the use of Bilastine in pregnant women.
The excretion of Bilastine in milk has not been studied in humans.

**Driving and using machines**
Bilastine 20 mg does not affect the driving performance in adults. However the response from each patient to the medicine may be different.

ACTOVERCO

Together for a healthy future

No. 58, 8th St., Kooye Nasr (Gisha St.), Tehran, IR Iran,
Postal Code: 1446863914, Telefax: +98 (21) 41637000
ACT.MKT.INT.08.1403.2690
**www.actoverco.com**