

BLEXTEN® was well-tolerated with treatment-emergent adverse reactions equal to those treated with placebo.1

Treatment-emergent adverse reactions reported in ≥ 1% of subjects treated with Bilastine in the double blind studies¹

Body system / AE	BLEXTEN® N=931	Placebo N=950
Gastrointestinal disorders	28 (3.01%)	28 (2.95%)
Abdominal pain upper	10 (1.07%)	4 (0.42%)
Nervous system disorders	81 (8.70%)	55 (5.79%)
Dizziness	10 (1.07%)	4 (0.42%)
Headache	40 (4.30%)	28 (2.95%)
Somnolence	38 (4.08%)	25 (2.63%)



Indications:

Seasonal Allergic Rhinitis

BLEXTEN® (bilastine) is indicated for the symptomatic relief of nasal and non-nasal symptoms of seasonal allergic rhinitis (SAR) in patients 4 years of age and older with a body weight of at least 16 kg.

Chronic Spontaneous Urticaria

BLEXTEN® (bilastine) is indicated for the relief of the symptoms associated with chronic spontaneous urticaria (CSU) (e.g. pruritus and hives), in patients 4 years of age and older with a body weight of at least 16 kg.

Contraindication:

• History of QT prolongation and/or torsade de pointes, including congenital long QT syndromes

Relevant warnings and precautions:

- QTc interval prolongation, which may increase the risk of torsade de pointes
- Use with caution in patients with a history of cardiac arrhythmias; hypokalemia, hypomagnesaemia; significant bradycardia; family history of sudden cardiac death; concomitant use of other QT/QTc-prolonging drugs
- P-glycoprotein inhibitors may increase plasma levels of BLEXTEN® in patients with moderate or severe renal impairment; co-administration should be avoided

- BLEXTEN® should be avoided during pregnancy unless advised otherwise by a physician
- A study was performed to assess the effects of BLEXTEN® and bilastine 40 mg on real time driving performance compared to placebo. Bilastine did not affect driving performance differently than placebo following day one or after one week of treatment. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

For more information:

Please consult the product monograph at https://www. miravohealthcare.com/wp-content/uploads/2021/08/ Blexten-PM-ENG-Aug2021.pdf for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The product monograph is also available by calling 1-866-391-4503.



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² As of August 31, 2021, the estimate from internal data of patient exposure is based on units sold of the defined daily dose of 20 mg bilastine and the mean treatment duration of 3 weeks.

Reference:

1. Blexten® Product Monograph. Aralez Pharmaceuticals Canada Inc. 2021.

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