

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE  
PATIENT MEDICATION INFORMATION**

**BLEXTEN®  
Bilastine Tablets**

Read this carefully before you start taking BLEXTEN and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about BLEXTEN.

**What is BLEXTEN used for?**

BLEXTEN is used to relieve the symptoms of:

- **Seasonal Allergic Rhinitis:** Hayfever (sneezing, itchy, runny, blocked-up nose, red and watery eyes) in patients 12 years of age and older.
- **Chronic Spontaneous Urticaria:** Hives and itching in patients 18 years of age and older.

**How does BLEXTEN work?**

BLEXTEN is an antihistamine - it blocks the action of histamine and relieves hayfever symptoms, itchiness and hives.

**What are the ingredients in BLEXTEN?**

Medicinal ingredient: bilastine

Non-medicinal ingredients: colloidal anhydrous silica, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

**BLEXTEN comes in the following dosage forms:**

Tablets: 20 mg

**Do not use BLEXTEN if:**

- You are allergic (hypersensitive) to bilastine or any of the other ingredients of BLEXTEN.
- You have a history of irregular heart beat.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BLEXTEN. Talk about any health conditions or problems you may have, including if you:**

- have kidney problems.
- have heart problems or a family history of heart problems.
- are pregnant or planning to becoming pregnant.
- are breastfeeding.

**Other warnings you should know about:**

**Driving and using machines**

While taking BLEXTEN you may experience a feeling of tiredness, which can affect your ability to drive or use machines. If you experience tiredness, do not drive or operate machinery.

BLEXTEN is not suitable for use by children under 12 years of age.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with BLEXTEN:**

- ketoconazole (used to treat fungal infections)
- erythromycin and rifampicin (used to treat bacterial infections)
- diltiazem (used to treat heart problems)
- cyclosporine (used to suppress the immune system)
- ritonavir (used to treat HIV/AIDS)
- grapefruit and other fruit juices

**How to take BLEXTEN:**

- Swallow the tablet with water.
- Take BLEXTEN on an empty stomach, one hour before eating or drinking or two hours after. Food and fruit juice will lower the amount of medicine available to treat your symptoms.
- Do not take more BLEXTEN than your healthcare professional has told you to. If your symptoms do not improve, consult your healthcare professional.

**Usual dose:**

**Seasonal Allergic Rhinitis (patients 12 years of age and older):** One tablet (20 mg) once daily.

**Chronic Spontaneous Urticaria (patients 18 years and older):** One tablet (20 mg) once daily.

**Overdose:**

If you think you have taken too much BLEXTEN, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget to take your dose on time, take it as soon as possible, and then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

**What are possible side effects from using BLEXTEN?**

These are not all the possible side effects you may feel when taking BLEXTEN. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- headache
- sleepiness
- dizziness
- stomach pain

BLEXTEN can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

<b>Serious side effects and what to do about them</b>				
Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Rare	<b>Heart problems:</b> heart racing or slowing, cold sweats, feeling faint, feeling your heart beat, light headed, nausea, shortness of breath			√
Unknown	<b>Allergic reactions:</b> difficulty in breathing, swelling of your face, lips, tongue or throat, and/or swelling and redness of the skin			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### **Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

#### **3 ways to report:**

- Online at [MedEffect \(www.healthcanada.gc.ca/medeffect\)](http://www.healthcanada.gc.ca/medeffect)
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 0701E  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Store between 15°C - 30°C.

Do not use BLEXTEN after the expiry date which is stated on the carton and the blisters after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Keep out of reach and sight of children.

### **If you want more information about BLEXTEN:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website \(www.healthcanada.gc.ca\)](http://www.healthcanada.gc.ca); the manufacturer's website [aralez.com](http://aralez.com), or by calling 1-866-391-4503.

This leaflet was prepared by Aralez Pharmaceuticals Trading DAC.

Last Revised: July 10, 2018