



PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

**P^rGLN-BILASTINE
Bilastine Tablets**

Read this carefully before you start taking **GLN-BILASTINE** 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 **GLN-BILASTINE**.

What is GLN-BILASTINE used for?

GLN-BILASTINE tablets are used to relieve the symptoms of:

- **Seasonal Allergic Rhinitis:** Hay fever (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 12 years of age and older.

How does GLN-BILASTINE work?

GLN-BILASTINE is an antihistamine - it blocks the action of histamine and relieves hay fever symptoms, itchiness and hives.

What are the ingredients in GLN-BILASTINE?

Medicinal ingredient: bilastine

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

GLN-BILASTINE comes in the following dosage forms:

Tablets: 20 mg

Do not use GLN-BILASTINE if:

- You are allergic (hypersensitive) to bilastine or any of the other ingredients of GLN-BILASTINE.
- You have a history of irregular heartbeat.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take GLN-BILASTINE. 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 GLN-BILASTINE 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.

GLN-BILASTINE tablets (20 mg) are 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 GLN-BILASTINE:

- 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 GLN-BILASTINE:

- Swallow the tablet with water.
- Take GLN-BILASTINE 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 GLN-BILASTINE 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: 1 tablet (20 mg) once daily.

Chronic Spontaneous Urticaria

Patients 12 years and older: 1 tablet (20 mg) once daily.

Overdose:

If you think you, or a person you are caring for, have taken too much GLN-BILASTINE, contact a 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 GLN-BILASTINE?

These are not all the possible side effects you may have when taking GLN-BILASTINE. If you experience any side effects not listed here, tell your healthcare professional.

- headache
- sleepiness
- dizziness
- stomach pain

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

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE Heart problems: heart racing or slowing, cold sweats, feeling faint, feeling your heart beat, light headed, nausea, shortness of breath			√
UNKNOWN Allergic reactions: 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, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health 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 to 30°C.

Do not use GLN-BILASTINE after the expiry date which is stated on the bottle, 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 GLN-BILASTINE:

- 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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); or by calling Glenmark Pharmaceuticals Canada Inc. at 1-844-801-7468.

This leaflet was prepared by:

Glenmark Pharmaceuticals Canada Inc.
Concord, ON L4K 4M2

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