Information For the User Bilastine (20mg)

Bilastuff 20 Tablet

Bilastine (20mg) Tablet: Product Information

Brand Name: Bilastine 20 mg Tablet

Generic Name: Bilastine **Strength**: 20 mg per tablet **Dosage Form**: Oral Tablet

Indications:

Bilastine 20 mg Tablet is an **antihistamine** primarily indicated for the treatment of allergic conditions, including:

1. Allergic Rhinitis:

 Management of symptoms associated with seasonal allergic rhinitis (hay fever) and perennial allergic rhinitis (year-round allergy), such as sneezing, runny nose, nasal itching, and itchy/watery eyes.

2. Chronic Urticaria (Hives):

 Relief of itching and rash associated with chronic idiopathic urticaria (chronic hives), a condition where red, itchy hives appear on the skin without an apparent cause.

Mechanism of Action:

Bilastine is a **second-generation antihistamine** that acts by selectively blocking **H1 histamine receptors**. Histamine is a substance produced by the body in response to allergens, leading to typical allergic symptoms like swelling, itching, and increased mucus production. Bilastine prevents histamine from binding to its receptors, thus helping to alleviate these symptoms without causing significant sedation or drowsiness (common with older antihistamines).

Dosage and Administration:

Adults and Children over 12 years:

- Recommended dose: Take 1 tablet (20 mg) once daily, preferably in the morning, with or without food
- The tablet should be swallowed whole with water. It should not be crushed or chewed.

Children (6 to 11 years):

 Recommended dose: 10 mg once daily. In this age group, Bilastine 10 mg tablets or other appropriate formulations may be preferred. Consult your healthcare provider for further guidance.

Children under 6 years:

 Bilastine 20 mg tablets are generally not recommended for children under the age of 6 unless prescribed by a healthcare provider.

Renal Impairment:

 In patients with moderate renal impairment, a dose reduction may be necessary. Consult your doctor for appropriate dosing recommendations.

Contraindications:

Bilastine 20 mg Tablet should not be used in the following conditions:

- **Hypersensitivity** (allergic reaction) to Bilastine or any of the excipients in the tablet.
- Severe renal impairment (reduced kidney function).

Warnings and Precautions:

- **Sedation**: Although Bilastine is a **non-sedating antihistamine**, rare cases of **drowsiness** or **fatigue** may occur, especially when used in combination with alcohol or other sedative drugs.
- Kidney Function: Use with caution in individuals with mild to moderate renal impairment, as the drug

- may accumulate in the body. In such cases, dosage adjustments may be necessary.
- Pregnancy and Breastfeeding: Bilastine should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus. It is not known whether Bilastine is excreted in breast milk, so consult your doctor before using this product if you are pregnant or breastfeeding.
- Elderly Patients: Caution is advised in elderly patients, especially those with renal impairment.

Side Effects:

Common side effects:

- Headache (most common side effect).
- **Drowsiness** or **mild fatigue** (rare and less common than with first-generation antihistamines).
- Dry mouth.
- **Stomach upset** (nausea or mild gastrointestinal discomfort).

Serious but rare side effects:

- Severe allergic reactions (such as rash, itching, swelling, difficulty breathing).
- Fast or irregular heartbeat (tachycardia).
- Severe dizziness or light-headedness.
- **Kidney issues**: Changes in urine output or signs of kidney dysfunction (e.g., swelling of the legs or feet).

If you experience any serious side effects or signs of an allergic reaction, seek immediate medical attention.

Drug Interactions:

- Erythromycin and Ketoconazole: These drugs can increase Bilastine levels in the blood, increasing the risk of side effects. Inform your healthcare provider if you are taking these medications.
- Antacids: Antacids containing aluminum or magnesium may reduce the absorption of Bilastine.
 If using antacids, allow a gap of at least 2 hours between taking Bilastine and the antacid.
- Alcohol and CNS Depressants: Although Bilastine is less sedating, alcohol and other CNS depressants may increase the sedative effects of Bilastine, leading to increased drowsiness and reduced alertness.

Storage:

- Store at **room temperature** (15°C to 30°C / 59°F to 86°F), away from moisture and heat.
- Keep the tablets in a **tightly closed container** to protect from light.
- Keep out of reach of children.

Patient Counseling Information:

- **Follow the prescribed dose**: Take Bilastine exactly as directed by your healthcare provider. Do not exceed the recommended dose.
- Be aware of possible side effects: If you experience severe drowsiness, dizziness, difficulty breathing, or swelling, seek immediate medical attention.
- Avoid alcohol: Alcohol may increase the sedative effects of Bilastine, leading to drowsiness or dizziness.
- Hydration: Drink plenty of water, especially if you experience dry mouth or gastrointestinal discomfort.
- Consult before combining with other medications: Inform your doctor if you are taking any other medicines, especially antacids, antifungals, or antibiotics that may interact with Bilastine.

This information for **Bilastine** (20 mg) **Tablet** outlines its uses, dosage, side effects, and safety precautions. Always consult your healthcare provider for personalized advice and recommendations before starting any medication.

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.)

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