

Beltas® 20mg Tablets

Bilastine 20mg

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1. What Beltas® 20mg Tablets is used for

Beltas® 20mg Tablets contains bilastine which is an antihistamine. Bilastine is used to relieve the symptoms of hayfever (sneezing, itchy, runny, blocked-up nose and red and watery eyes) and other forms of allergic rhinitis. They may also be used to treat itchy skin rashes (hives or urticaria).

2. How Beltas® 20mg Tablets Works

Bilastine is a non-drowsy, long-acting antihistamine that helps to relieve symptoms of allergy such as sneezing, tearing and itching. It blocks the effects of histamine, a chemical substance produced by the body in response to foreign substances which the body is allergic to.

3. Before you use Beltas® 20mg Tablets

- When you must not take it

Do not take it if you are allergic (hypersensitive) to bilastine or any of the other ingredients of Beltas® 20mg Tablets (see **Product Description**).

Do not give this medicine to children under 12 years of age. Ask your doctor or pharmacist for appropriate dosages in children under 12 years.

- Before you start to take it

Inform your doctor if you have moderate or severe renal impairment and you are taking other medicines (see *-Taking other*

medicines)

- Driving and using machines

It has been demonstrated that bilastine 20 mg does not affect the driving performance in adults.

However the response from each patient to the medicine may be different. Therefore you should check how this medicine affects you, before driving or operating machinery.

Bilastine intake with alcohol, at the recommended dose (20 mg), does not increase the drowsiness caused by alcohol.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, please discuss with your doctor if you are taking any of the following medicines:

- Ketoconazole (an antifungal medicine)
- Erythromycin (an antibiotic)
- Diltiazem (to treat angina)
- Cyclosporine (to reduce the activity of your immune system, thus avoiding transplant rejection or reducing disease activity in autoimmune and allergic disorders, such as psoriasis, atopic dermatitis or rheumatoid arthritis)
- Ritonavir (to treat AIDS)
- Rifampicin (an antibiotic)

4. How to take Beltas® 20mg Tablets

Always take this medicine exactly as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Swallow your tablet with a glass of water.

Note: The score line is only meant to facilitate breaking for ease of swallowing, and not meant to be divided into two equal doses.

- How much to take

Adults, including the elderly and adolescents aged 12 years and over: take one tablet daily.

- When to take it

The tablet must be taken on an empty stomach, one hour before or two hours after intake of food or fruit juice.

These tablets should not be taken with **food or with grapefruit juice or other fruit juices**, as this will decrease the effect of bilastine. To this, you can:

- take the tablet and wait for one hour before taking food or fruit juice or
- if you have taken food or fruit juice, wait for two hours before taking the tablet.

- How long to take it

Your physician will determine the type of disease you are suffering from and will determine for how long you should take Beltas® 20mg Tablets.

- If you forget to take it

If you forget to take your dose on time, take it as soon as you remember, and then go back to your regular dosing schedule. If it is almost time for your next dose, wait until then to take the medicine. Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this product, ask your doctor or pharmacist.

- If you take too much (overdose)

If you, or anyone else, have taken too many Beltas® 20mg Tablets, contact your doctor or pharmacist immediately or go to the emergency department of your nearest hospital. Please remember to take this medicine pack or this leaflet with you.

5. While you are using Beltas® 20 mg Tablets

- Things you must do

- Take the medicine as prescribed by your doctor.
- Inform your doctor or pharmacist if you have any allergic reaction to this medication.
- If symptoms persist consult your doctor.

- Things you must not do

- Do not exceed the recommended dose.
- Do not let anyone else use your medication.

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- Things to be careful of

Contact your doctor if you are pregnant, likely to become pregnant or breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

6. Side effects

Like all medicines, Beltas® 20mg Tablets can cause side effects, although not everybody gets them.

If you experience symptoms of an allergic reaction the signs of which may include difficulty in breathing, dizziness, collapsing or losing consciousness, swelling of your face, lips, tongue or throat, and/or swelling and redness of the skin, stop taking the medicine and seek urgent medical advice straight away.

Other side effects that may be experienced in adults and adolescents are:

Common: may affect 1 to 10 users in 100

- Headache
- Drowsiness

Uncommon: may affect up to 1 in 100 people

- Abnormal ECG heart tracing
- Blood tests which show changes in the way the liver is working
- Dizziness
- Stomach pain
- Tiredness
- Increased appetite
- Irregular heartbeat
- Increased weight
- Nausea (the feeling of being sick)
- Anxiety
- Dry or uncomfortable nose
- Belly pain
- Diarrhoea
- Gastritis (inflammation of the stomach wall)
- Vertigo (a feeling of dizziness or spinning)
- Feeling of weakness
- Thirst
- Dyspnea (difficulty in breathing)
- Dry mouth

- Indigestion
- Itching
- Cold sores (oral herpes)
- Fever
- Tinnitus (ringing in the ears)
- Difficulty in sleeping
- Blood tests which show changes in the way kidney is working
- Blood fats increased

Frequency not known: cannot be estimated from the available data

- palpitations (feeling your hear beat)
- tachycardia (fast heart beat)
- Vomiting

Uncommon: may affect up to 1 in 100 people

- eye irritation
- dizziness
- loss of consciousness
- diarrhoea
- nausea (the feeling of being sick)
- lip swelling
- eczema
- urticaria (hives)
- fatigue

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and Disposal of Beltas®

- Storage

Store below 30°C.

- Disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

8. Product Description

- What it looks like

White to off white, oval, biconvex uncoated tablet debossed with "Y41" on one side and

scored on the other side.

Note: The score line is only meant to facilitate breaking for ease of swallowing, and not meant to be divided into two equal doses.

-Pack size(s)

1 X 10 Tablets, 3 X 10 Tablets, 5 X 10 Tablets

Note: Not all pack sizes may be marketed.

- Ingredients

- Active ingredient(s)

Bilastine

- Inactive ingredients

Microcrystalline Cellulose, Sodium Starch Glycolate, Silica Colloidal Anhydrous, Magnesium Stearate.

- MAL number:

MAL24106024AZ

9. Manufacturer & Product Registration Holder

Manufacturer

Glenmark Pharmaceuticals Ltd
Plot No. S-7, Colvale Industrial Estate, Colvale,
Bardez, Goa – 403513, India

Product Registration Holder

Glenmark Pharmaceuticals (Malaysia) Sdn Bhd
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10. Date of revision

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