BILADRIVE-20 TABLETS

Bilastine 20 mg

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What Biladrive-20 is used for

Biladrive-20 contains bilastine which is an antihistamine. Biladrive-20 is used to relieve the symptoms of hay fever (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).

How Biladrive-20 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.

Before you use Biladrive-20

- When you must not use it

Do not take it if you are allergic (hypersensitive) to bilastine or any of the other ingredients of Biladrive-20.

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

Other form of this medicine – bilastine 10 mg orodispersible tablets or bilastine 2.5 mg/mL oral solution may be more suitable for children 6 to 11 years old with a body weight of at least 20 kg.
Do not give Bilastine to children under 6 years with a body weight below 20 kg since no sufficient data is available.

- Before you start to use it

Inform your doctor if you have moderate or severe renal impairment and if you are taking other medicines.

- 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.
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)

How to take Biladrive-20

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Swallow your tablet with a glass of water. The score line is not intended to divide the tablet into equal doses. It can be used to break the tablet and make swallowing easier.

- How much to use

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

- When to use 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 avoid 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 use it

Your physician will determine the type of disease you are suffering from and will determine for how long you should take Buladrive-20.

- If you forget to use 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 use too much (overdose)

If you, or anyone else, have taken too many Biladrive-20, 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.

While you are using it

- 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.

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Bilastine 20 mg

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.

- 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.

Driving and using machines

It has been demonstrated that bilastine 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.

Side effects

Like all medicines, Biladrive-20 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 heartbeat)
- tachycardia (fast heartbeat)
- 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 www.npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Biladrive

Storage

Keep out of the reach and sight of children.
Store below 30°C.

- Disposal

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.

Product Description

- What it looks like

White to off-white, oval shaped tablets, with break line on one side and plain on other side, packed in Alumnium-Aluminium blister.

- Ingredients

- Active ingredient
Bilastine

- Inactive ingredients
Microcrystalline Cellulose, Sodium starch glycolate, Silica, colloidal Anhydrous, Magnesium stearate

- MAL number:

MAL**********

BILADRIVE-20 TABLET

Bilastine 20 mg

Manufacturer
Athena Drug Delivery Solutions Pvt. Ltd.
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Ambernath (West),
Maharashtra, 421 501,
India

Product Registration Holder
Mega Lifesciences Sdn. Bhd.
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