BILADRIVE-20 ODT

Bilastine 20 mg

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What Biladrive-20 ODT is used for

Biladrive-20 ODT contains bilastine which is an antihistamine. Biladrive-20 ODT 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 ODT 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 ODT

- 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 ODT.

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 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 ODT

- How much to use

Biladrive-20 ODT is indicated in adults and adolescents (12 years and above).

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

Adults and adolescents

1 orodispersible tablet once daily for the relief of symptoms of allergic rhino-conjunctivitis and urticaria.

- The orodispersible tablet is for oral use.
- Please place the orodispersible tablet in the mouth. It will disperse rapidly in saliva and can then be easily swallowed.
- Alternatively, you may disperse the orodispersible tablet in a water before taking it.
- You should use exclusively water for dispersion, do not use grapefruit juice or any other fruit juices.

- When to use it

You should take the orodispersible tablet one hour before or two hours after intake of food or fruit juice.

- How long to use it

Continue taking product name for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. In any case, do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

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

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.

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 ODT 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

- Headache
- Drowsiness

Uncommon

- 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

- palpitations (feeling your heartbeat)
- tachycardia (fast heartbeat)
- Vomiting

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

Storage and Disposal of Biladrive-20 ODT

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, round, biconvex tablets with plain surface on both sides, packed in Alumnium-Aluminium blister.

- Ingredients

- Active ingredient
  Bilastine

- Inactive ingredients
  Microcrystalline Cellulose, Mannitol, Sucralose, Silica Colloidal Anhydrous, Purified water, Crosspovidone, Masking flavour, Strawberry flavour, Magnesium stearate

- MAL number:

MAL26086136ACZ

Manufacturer

Athena Drug Delivery Solutions Pvt. Ltd.
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Product Registration Holder

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