

# ACCORD BISOPROLOL

Bisoprolol Fumarate (5 mg, 10 mg)

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## What ACCORD BISOPROLOL is used for

Bisoprolol 5 mg and 10 mg Tablets are used in combination with other medicines to treat chronic heart failure.

Bisoprolol 5 mg and 10 mg tablets are also used to treat high blood pressure (Hypertension) and angina pectoris (Chest pain caused by blockages in the arteries that supply the heart muscle).

## How ACCORD BISOPROLOL works

The active ingredient in this medicine is Bisoprolol fumarate. Bisoprolol Tablets belongs to group of medicines called beta-blockers.

## Before you use ACCORD BISOPROLOL

- When you must not use it if you  
- are allergic (Hypersensitive) to Bisoprolol fumarate or any of the other ingredients of Bisoprolol Tablets.

- have severe asthma or severe chronic lung disease.
- have severe blood circulation problem in your limbs (such as Raynaud's syndrome), which may cause your fingers and toes to tingle or turn pale or blue.
- have untreated phaeochromocytoma, a rare tumour of the adrenal gland (medulla).
- have metabolic acidosis, a condition when there is too much acid in the blood.
- have heart failure that suddenly becomes worse and / or that may require hospital treatment
- have a slow heart rate
- have very low blood pressure
- have a slow or irregular heart rate (less than 60 beats per minute). Ask your doctor if you are not sure.

## - Before you start to use it

Tell your doctor or pharmacist before starting to take ACCORD BISOPROLOL if you:

- have asthma or chronic lung disease
- have diabetes. Bisoprolol can hide the symptoms of low blood sugar
- are fasting from solid food
- are treated for hypersensitivity (allergic) reactions. Bisoprolol may make your allergy worse or more difficult to treat.
- have any heart problems
- have any liver or kidney problems
- have any problems with the circulation in your limbs
- are going to be given a general anaesthetic during an operation – tell your doctor that you are taking bisoprolol

- are taking verapamil or diltiazem, medicines used to treat heart conditions.
- Concomitant use is not recommended, see also "taking other medicines"
- have (or have had) psoriasis (a recurring skin rash)
- have phaeochromocytoma (a rare tumour of the adrenal gland). Your doctor will need to treat this before prescribing bisoprolol for you
- have a thyroid problem. The tablets can hide symptoms of an overactive thyroid.

## - Taking other medicines

Tell your doctor if you are already taking or using any of the following as they may interact with your medicine:

- medicines for controlling the blood pressure or medicines for heart problems (such as amiodarone, amlodipine, clonidine, digitalis glycosides, diltiazem, disopyramide, felodipine, flecainide, lidocaine, methyl dopa, moxonidine, propafenone, quinidine, rilmenidine, verapamil, phenytoin)
- medicines to treat reduction of heart rate (eg. Digitalis Glycosides)
- medicines such as tricyclic anti-depressants, barbiturates, phenothiazines
- medicines used for anaesthesia during an operation
- Non-steroidal anti-inflammatory drugs (NSAIDs)
- medicines for asthma or medicines used for a blocked nose
- medicines used for certain eye disorders such as glaucoma (increased pressure in the eye)

or used to widen the pupil of the eye (e.g. topical beta-blockers)

- certain medicines to treat clinical shock (e. g. adrenaline, dobutamine, noradrenaline)
- mefloquine, a medicine for malaria
- all these drugs as well as bisoprolol may influence the blood pressure and/or heart function.(Monoamine oxidase inhibitors {except MAO-B inhibitors})
- $\beta$ -Sympathomimetic agents (e.g. isoprenaline)
- Insulin and oral antidiabetic drugs
- rifampicin for the treatment of infections
- medicines to treat severe headaches or migraines (ergotamine derivatives).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

### **How to take ACCORD BISOPROLOL**

#### - How much to use

Always take Bisoprolol Tablets exactly as your doctor has told you. You should check with your doctor or your pharmacist if you are not sure.

Adult:

*Chest pain and high blood pressure:*

Your doctor will start the treatment with lowest possible dose (5 mg). Your doctor will monitor you closely at the start of treatment. Your doctor will increase your dose to obtain the best possible dosage for you.

The maximum recommended dose is 20 mg once per day.

Patient with kidney disease:

Patient with severe kidney disease should not exceed 10 mg of bisoprolol once daily.

Please consult your doctor before starting to use this medicine.

Patient with liver disease:

Patient with severe liver disease should not exceed 10 mg of bisoprolol once daily.

Please consult your doctor before starting to use this medicine.

#### *Heart failure:*

Before you start using Bisoprolol Tablets, you should already be taking other medicines for heart failure including any ACE inhibitor, a diuretic and (as an added option) a cardiac glycoside.

Treatment with Bisoprolol Tablets must be started at a low dose and increased gradually. Your doctor will decide how to increase the dose, and this will normally be done in the following way:

- 1.25 mg bisoprolol fumarate once daily for a week
- 2.5 mg bisoprolol fumarate once daily for a week
- 3.75 mg bisoprolol fumarate once daily for a week
- 5 mg bisoprolol fumarate once daily for four weeks
- 7.5 mg bisoprolol fumarate once daily for four weeks
- 10 mg bisoprolol fumarate once daily for maintenance (on-going) therapy.

The maximum recommended daily dose of bisoprolol fumarate is 10 mg.

Children:

Bisoprolol Tablets is not recommended for use in children.

Elderly patient:

In general adjustment of the dose is not needed. It is recommended to start with lowest possible dose. If you notice that the bisoprolol dose is too strong or does not work well enough, please consult your doctor or pharmacist.

#### - When to use it

Always follow your doctor's, or pharmacist's advice about how and when to take your medicine. Treatment with Bisoprolol Tablets requires regular medical checkup. This is particularly important in the initiation of therapy and during dose increase. Bisoprolol Tablets should be taken in the morning, with or without food. Swallow the tablet/s whole with some water and do not chew or crush them.

#### - How long to use it

Treatment with Bisoprolol Tablets is usually prolonged.

Depending on how well you tolerate the medicine, the doctor may also extend the time between dose increases. If your condition gets worse or if you no longer tolerate the drug, it may be necessary to lower the dose again or to stop treatment. For some patients a maintenance dose lower than 10 mg bisoprolol fumarate may be sufficient.

Your doctor will tell you what to do. If you have to stop the treatment entirely, your doctor will usually advise you to reduce the dose gradually, as otherwise your condition may become worse.

#### - If you forget to use ACCORD BISOPROLOL

If you forget to take a dose, take it as soon as you remember it unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

#### - If you use too much (Overdose)

If you take too much medicine, or if a child has swallowed the medicine by mistake ask your doctor or hospital for assessing risk and advice. Take this leaflet and any tablets you still have with you. You may feel slow heartbeat, severe breathing

difficulties, dizziness or tremor (due to decreased blood sugar).

### **While you are using ACCORD BISOPROLOL**

#### **- Things you must do**

Always follow your doctor's, or pharmacist's advice about how and when to take your medicine.

#### **- Things you must not do**

Do not stop treatment suddenly or change the recommended dose without talking to your doctor first. If you need to stop treatment, it must be done gradually to avoid side effects.

#### **- Things to be careful of**

**Pregnancy and breast-feeding:**  
There is a risk that Bisoprolol Tablets can harm the baby if it is used during pregnancy. If you are pregnant or plan to become pregnant you should tell your doctor. He or she will determine whether you can take Bisoprolol Tablets during pregnancy. It is not known whether Bisoprolol fumarate passes in to breast milk. Therefore, breastfeeding is not recommended during treatment with Bisoprolol Tablets.

#### **Driving and using machine:**

The ability to drive or operate machinery may be affected, depending on how well you tolerate the medicine. Be especially careful at the beginning of the treatment, when the dose is increased or when the medication is changed, and when combined with alcohol.

### **Side effects**

#### **Common side effects:**

cold hands and/or feet,  
numbness of hands and/or feet,  
low blood pressure, feeling sick,  
vomiting, diarrhoea,  
constipation, tiredness\*, feeling weak, dizziness\*, headache\*,  
worsening of irregular heartbeat,

inflammation of the liver (hepatitis) causing abdominal pain, loss of appetite and sometimes jaundice with yellowing of the whites of the eyes and skin and dark urine, fainting.

\*if treated for high blood pressure or angina then these symptoms occur especially at the beginning of treatment, or if your dosage changes. They are generally mild and often disappear within 1 to 2 weeks.

If any of the side effects get serious or if any side effect is noticed which is 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](http://npa.gov.my) [Consumers -> Reporting Side Effects to Medicines”

### **Storage and disposal of Accord Bisoprolol**

#### **- Storage**

- Do not store above 30°C.
- DO NOT use tablets after the expiry date that is printed on the label. The expiry date refers to the last day of that month.
- Keep out of the reach and sight of children.

#### **- 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**

ACCORD BISOPROLOL 5:  
White to off white, round, biconvex, film coated tablets, debossed 'b2' on one side and break line on other side. Thickness is between 2.85 mm to 3.55 mm

ACCORD BISOPROLOL 10:  
White to off white, round, biconvex, film coated tablets, debossed 'b3' on one side and break line on other side. Thickness is between 3.80 mm to 4.80 mm

### **Ingredients**

#### **- Active ingredient**

Bisoprolol fumarate

#### **- Inactive ingredients**

- Microcrystalline Cellulose
- Sodium Starch Glycolate (Type A)
- Povidone K30
- Colloidal Anhydrous Silica
- Magnesium Stearate
- Hydroxy Propyl Methyl Cellulose E-15
- Polyethylene Glycol 400
- Titanium Dioxide
- Purified Talc

### **MAL Numbers:**

ACCORD BISOPROLOL 5:  
MAL18086116AZ  
ACCORD BISOPROLOL 10:  
MAL18086124AZ

### **Manufacturer:**

INTAS PHARMACEUTICALS LIMITED  
Plot No 5-14, Pharmez, Near Village Matoda, Sarkhej-Bavla National Highway No. 8-A, Sanand Taluka, Ahmedabad, Gujarat, IN 382213, India

### **Product**

#### **Registration Holder:**

Accord Healthcare Sdn. Bhd.  
Suite 12A-15, Level 12A, Wisma Zelan  
No 1 Jalan Tasik Permaisuri 2 Bandar Tun Razak  
56000 Kuala Lumpur

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#### **Serial No:**

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