

BISODAC-HF 2.5/5/10mg (Bisoprolol Fumarate Tablets 2.5mg/ 5 mg/ 10 mg)

Bisoprolol Fumarate (2.5mg, 5mg & 10mg)

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What BISODAC-HF is used for

Bisodac-HF 2.5 mg is used for:

- Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and

Bisodac-HF 5mg & 10 mg is used for:

- Treatment of high blood pressure (hypertension)
- Treatment of coronary heart disease (angina pectoris)
- Treatment of stable chronic heart failure with reduced systolic left ventricular function in addition to ACE inhibitors, and diuretics, and optionally cardiac glycosides.

How BISODAC-HF works

Heart failure occurs when the heart muscle is weak and unable to pump enough blood around the circulation. This results in breathlessness and swelling. Bisoprolol slows

down the heart rate and makes the heart more efficient at pumping blood around the body.

Before you use BISODAC-HF

- When you must not use it

- are allergic (hypersensitivity) to bisoprolol or to any of the other ingredients of BISODAC-HF.
- have severe asthma or severe chronic lung disease
- have severe blood circulation problems in your limbs (such as Raynaud's syndrome), that may cause your fingers and toes to tingle or turn pale or blue
- have untreated phaeochromocytoma, as rare tumour of the adrenal gland
- 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 or irregular heart rate: ask your doctor if you are not sure
- have very low blood pressure
- shock induced by disorders of cardiac function (cardiogenic shock),
- severe disturbances of atrioventricular conduction (second or third degree AV block) without a pacemaker,
- sick sinus syndrome,
- sinoatnal block

- Before you start to use it

If you have any of the following conditions tell your doctor before taking bisoprolol; he or she may

want to take special care (for example give additional treatment or perform more frequent checks):

- diabetes (bisoprolol can hide the symptoms of low blood sugar)
- strict fasting
- any heart disease
- kidney or liver problems
- any blood circulation problems in your limbs
- asthma or chronic lung disease
- psoriasis, now or in the past
- tumour of the adrenal gland (pheochromocytoma)
- thyroid disorder (bisoprolol can hide the symptoms of an overactive thyroid).
- mild disturbances of atrioventricular conduction (first degree AV block),
- disturbed blood flow in the coronary vessels due to vasospasms (Prinzmetal's angina),
- peripheral arterial occlusive disease (aggravation of symptoms may occur especially when starting therapy)

In addition, tell your doctor if you are going to have:

- desensitization therapy (for example for the prevention of hay fever), because bisoprolol may make it more likely that you experience an allergic reaction, or such reaction may be more severe
- anaesthesia (for example for surgery), because bisoprolol may influence how your body reacts to this situation.

Pregnancy and breast-feeding

There is a risk that use of bisoprolol during pregnancy may harm the baby. If you are pregnant or planning to become pregnant, tell your doctor. He or she will decide whether you can take bisoprolol during pregnancy. It is not known whether bisoprolol passes into human breast milk. Therefore, breastfeeding is not recommended during therapy with bisoprolol.

- **Taking other medicines**
Please tell your doctor or pharmacist if you are taking or having recently taken any other medicines. This includes any medicines which you have bought without a prescription.

How to use BISODAC-HF

- **How much to use**

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

For high blood pressure and chest pain, 5 to 10mg taken orally as a single daily dose. The maximum recommended dose is 20mg daily.

For stable chronic heart failure, please take the dose as prescribed by the doctor.

Your doctor or pharmacist will prescribe other doses based on individual conditions.

- **When to use it**
Take the tablet with some water in the morning, with

or without food. Do not crush or chew the tablet.

- **How long to use it**
Follow the prescription from your doctor or pharmacist.

Do not stop treatment suddenly or change the dose without consulting your doctor first.

- **If you forget to use it**
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)**
Contact your doctor or local emergency ward immediately. Take this leaflet and any tablets you still have with you. Your doctor will decide what measures are necessary. Symptoms of an overdose may include:

- dizziness, light-headedness, fatigue
- breathing difficulties
- slowed heart rate, low blood pressure
- feelings of hunger, sweating and palpitations (caused by low blood sugar).

While you are using it

- **Things you must do**
Before you start using Bisoprolol Fumarate, you should already be taking other medicines for heart failure including an ACE-inhibitor, a diuretic and (as an added option) a cardiac glycoside.

Always take bisoprolol exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Treatment with bisoprolol requires regular monitoring by your doctor. This is particularly necessary at the start of treatment and during dose increase.

Take the tablet with some water in the morning, with or without food. Do not crush or chew the tablet.

- **Things you must not do**

Do not chew the tablets.

Do not take this medicine by yourself without prescription from your doctor or pharmacist.

- **Things to be careful of**
Driving and using machines

Your ability to drive or use machinery may be affected depending on how well you tolerate this medicine. Please be especially cautious at the start of treatment, when the dose is increased or the medication is changed, as well as in combination with alcohol.

Side effects

Like all medicines, bisoprolol can cause side effects, although not everybody gets them.

The following side effects are important and will require immediate action if you experience them.

You should stop taking bisoprolol and see your doctor immediately if the following symptoms occur:

Common effects:

- Worsening of heart failure causing increased breathlessness and / or retention of fluid.

- tiredness, feeling weak, dizziness, headache
- feeling of coldness or numbness in hands or feet
- low blood pressure
- nausea, vomiting, diarrhoea, or constipation.
- asthenia (in patients with chronic heart failure), fatigue

Very Common:

- bradycardia- slowing down of heart rate (in patients with chronic heart failure)

Uncommon:

- sleep disturbances
- depression
- breathing problems in patients with asthma or chronic lung disease
- muscle weakness, muscle cramps
- AV-conduction disturbances; bradycardia (in patients with hypertension or angina pectoris); worsening of pre-existing heart failure (in patients with hypertension or angina pectoris)
- asthenia (in patients with hypertension or angina pectoris)

Rare:

- hearing problems
- allergic runny nose
- reduced tear flow (important if you use contact lenses)
- inflammation of the liver which can cause yellowing of the skin or whites of the eyes
- changes in blood test results
- allergy-like reactions such as itching, flush, rash
- reduced sexual potency
- nightmares, hallucinations
- Hepatitis

Very rare:

- irritation and redness of the eye (conjunctivitis)
- hair loss
- Cause or worsen a skin rash similar to psoriasis.

Tell your doctor or your pharmacist if you notice any of the side effects listed above or any other unwanted or unexpected effects.

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.moh.gov.my (Consumers -> Reporting -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of BISODAC-HF

- Storage
Do not store above 30°C.

Keep out of the reach and sight of children.

Do not use bisoprolol after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last date of that month.

- 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

BISODAC-HF 2.5 (Bisoprolol Fumarate Tablets 2.5mg):

White, circular, biconvex, film-coated tablets, debossed with 'P and breakline' on one side and '2' on the other side.

10's & 14's blister of cold form (Alu-alu) blister with peelable lidding foil or cold form (Alu-alu) blister with push through lidding foil.

BISODAC-HF 5mg (Bisoprolol Fumarate Tablets 5 mg):

White, circular, biconvex, film-coated tablets, debossed with 'P and breakline' on one side and '5' on the other side.

10's & 14's blister of cold form (Alu-alu) blister with peelable lidding foil or cold form (Alu-alu) blister with push through lidding foil.

BISODAC-HF 10 (Bisoprolol Fumarate Tablets 10mg):

White, circular, biconvex, film-coated tablets debossed with 'P and breakline' on one side and '10' on the other side.

10's & 14's blister of cold form (Alu-alu) blister with peelable lidding foil or cold form (Alu-alu) blister with push through lidding foil.

- Ingredients:

Active ingredient (s)

Bisoprolol Fumarate

Inactive ingredients

Cellulose microcrystalline, calcium hydrogen phosphate anhydrous, silica colloidal anhydrous, crospovidone, magnesium stearate, opadry white and purified water.

MAL number:

BISODAC-HF 2.5 (Bisoprolol Fumarate Tablets 2.5mg):

MAL18106132AZ

BISODAC-HF 5 (Bisoprolol Fumarate Tablets 5 mg) :

MAL15045126AZ

BISODAC-HF 10 (Bisoprolol Fumarate Tablets 10mg):

MAL18106135AZ

Manufacturer

**Aurobindo Pharma Limited
(Unit III),**

Unit –III Sy.Nos. 313 & 314,
Bachupally (V), Bachupally
Mandal,
Medchal - Malkajgiri District,
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Product Registration Holder

Unimed Sdn Bhd

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10/04/2020

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