

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Bisoprolol Fumarate Inovamed 2.5 mg,

Bisoprolol Fumarate Inovamed 5 mg,

Bisoprolol Fumarate Inovamed 10 mg

Each Bisoprolol Fumarate Inovamed 2.5 mg film-coated tablet contains:

Bisoprolol fumarate 2.5 mg

Each Bisoprolol Fumarate Inovamed 5 mg film-coated tablet contains:

Bisoprolol fumarate 5 mg

Each Bisoprolol Fumarate Inovamed 10 mg film-coated tablet contains:

Bisoprolol fumarate 10 mg

For a list of inactive and allergenic ingredients in the preparation, see section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

• Keep the leaflet; you may need it again.

• This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Bisoprolol Fumarate Inovamed 2.5 mg is intended for the treatment of chronic conditions of moderate to severe stable heart failure, in combination with other medicines.

Bisoprolol Fumarate Inovamed 5 mg and Bisoprolol Fumarate Inovamed 10 mg are intended for the treatment of hypertension and angina pectoris. This medicine is also intended for the treatment of chronic conditions of moderate to severe stable heart failure, in combination with other medicines.

Therapeutic group:

Selective beta-blockers.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to bisoprolol or to any of the ingredients contained in the medicine (see section 6 "Further information")
- You suffer from severe asthma
- You suffer from a severe blood circulation problem in your limbs (such as Raynaud's syndrome), a syndrome that may cause your fingers or toes to tingle, turn pale or blue
- You suffer from untreated pheochromocytoma, which is a rare tumor of the adrenal gland
- You suffer from metabolic acidosis – a condition in which there is too much acid in the blood
- You are suffering from acute heart failure
- You are suffering from worsening heart failure requiring injection of medicines into a vein, which increase the force of contraction of the heart
- You suffer from a slow heart rate
- You suffer from low blood pressure
- You suffer from various heart conditions causing a very slow heart rate or an abnormal heartbeat
- You are suffering from cardiogenic shock (originating in the heart). This is a serious heart condition causing low blood pressure and circulatory failure

Special warnings regarding use of the medicine Before beginning treatment with Bisoprolol Fumarate Inovamed, tell the doctor if:

- You suffer from diabetes
- You are strictly fasting
- You suffer from certain heart diseases such as disturbances in heart rhythm or severe chest pain at rest (Prinzmetal's angina)
- You suffer from kidney or liver problems
- You have less severe blood circulation problems in your limbs
- You suffer from chronic lung disease or less severe asthma
- You have a history of a scaly skin rash (psoriasis)
- You suffer from tumors in the adrenal gland (pheochromocytoma)
- You suffer from thyroid gland disorders

Your doctor may wish to be especially cautious (for example, give additional treatment or perform more frequent checks).

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

- Desensitization therapy (for example, for the prevention of hay fever), because Bisoprolol Fumarate Inovamed may increase the chance of experiencing an allergic reaction, or this reaction may be more severe
- Anesthesia (for example for surgery), because Bisoprolol Fumarate Inovamed may affect your body's response to the anesthetic process

If you suffer from chronic lung disease or less severe asthma, inform your doctor immediately if you start to experience new difficulties in breathing, cough, wheezing after exercise or similar effects while using Bisoprolol Fumarate Inovamed.

Children and adolescents

This medicine is not recommended for use by children and adolescents.

Tests and follow-up

Treatment with Bisoprolol Fumarate Inovamed requires regular monitoring by your doctor. The monitoring is particularly necessary at the start of treatment, during dose increase and when you stop treatment.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Do not take the following medicines with Bisoprolol Fumarate Inovamed without consulting your doctor:

- Certain medicines for the treatment of irregular or abnormal heartbeat (Class I antiarrhythmic medicines such as quinidine, disopyramide, lidocaine, phenytoin, flecainide, propafenone).
- Certain medicines for the treatment of high blood pressure, angina pectoris or irregular heartbeat (calcium channel blockers called verapamil and diltiazem).
- Certain medicines for the treatment of high blood pressure, such as clonidine, methyldopa, moxonidine and rilmenidine. However, **do not stop taking these medicines** without consulting with your doctor.

Check with the doctor before taking the following medicines with Bisoprolol Fumarate Inovamed; the doctor may need to check your condition more frequently:

- Certain medicines for the treatment of high blood pressure or angina pectoris (calcium channel blockers from the dihydropyridine group, such as felodipine and amlodipine).
- Certain medicines for the treatment of irregular or abnormal heartbeat (Class III antiarrhythmic medicines such as amiodarone).
- Beta-blockers applied locally (such as timolol eye drops for the treatment of glaucoma).
- Certain medicines for the treatment of Alzheimer's disease or glaucoma (parasympathomimetic medicines such as tacrine or carbachol) or medicines used to treat severe heart problems (sympathomimetic medicines such as dobutamine, isoprenaline).
- Medicines for the treatment of diabetes, including insulin.
- Anesthetics (for example during surgery).
- Digitalis, for the treatment of heart failure.
- Non-steroidal anti-inflammatory drugs (NSAIDs) for the treatment of arthritis, pain or inflammation (such as ibuprofen or diclofenac).
- Any medicine that can cause reduced blood pressure, whether intended or not, such as medicines for reducing blood pressure, certain medicines for depression (tricyclic antidepressants such as imipramine or amitriptyline), certain medicines for the treatment of epilepsy or during anesthesia (barbiturates such as phenobarbital), or certain medicines for the treatment of mental illnesses characterized by a loss of contact with reality (phenothiazines such as levomepromazine).
- Mefloquine, a medicine for the treatment or prevention of malaria.
- Antidepressant medicines called MAO inhibitors (except MAO-B inhibitors) such as moclobemide.

Use of the medicine and food

Take the tablet in the morning with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, consult with a doctor or pharmacist before using medicines.

There is a risk that use of Bisoprolol Fumarate Inovamed during pregnancy may harm the unborn baby. If you are pregnant or planning to become pregnant, tell your doctor and he will decide whether you should take Bisoprolol Fumarate Inovamed during pregnancy. It is not known whether bisoprolol passes into breast milk. Therefore, breastfeeding is not recommended during treatment with Bisoprolol Fumarate Inovamed.

Driving and operating machinery

The ability to drive or to operate machinery could be affected by the use of Bisoprolol Fumarate Inovamed, depending on your ability to adapt to the medicine. Caution is necessary, especially at the beginning of treatment, when the dose of the medicine is increased, when changes are made in medicinal treatment, or after consuming alcohol.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only.

Treatment with Bisoprolol Fumarate Inovamed must be started at a low dose and increased gradually. Your doctor will decide how to increase the dose.

The usual dose is generally:

Treatment of chronic conditions of stable heart failure

The increase in dose will normally be done in the following way:

1.25 mg bisoprolol once daily for one week

2.5 mg bisoprolol once daily for one week

3.75 mg bisoprolol once daily for one week

5 mg bisoprolol once daily for 4 weeks

7.5 mg bisoprolol once daily for 4 weeks

10 mg bisoprolol once daily for continued treatment as a long-term (ongoing) maintenance dose.

The highest recommended daily dose is 10 mg bisoprolol.

Depending on how well you tolerate the medicine, your doctor may lengthen the time until increasing the dose.

If your condition gets worse or you are no longer able to tolerate the medicine, it may be necessary to reduce the dose of the medicine again or to interrupt treatment.

In some patients, a long-term dose of less than 10 mg bisoprolol may be sufficient.

Your doctor will instruct you as to what to do.

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

Treatment of hypertension

The recommended treatment regimen is 5 mg, once daily. In cases of mild hypertension, your doctor may determine that a dosage regimen of 2.5 mg once daily will be sufficient.

If necessary, the doctor may instruct you to increase the dose of the medicine to 10 mg, once daily.

Treatment of angina pectoris

The recommended treatment regimen is 5 mg, once daily.

If the response is inadequate, your doctor may instruct you to increase the dose of the medicine to 10 mg, once daily.

Dosage in patients with impaired liver or kidney function

Patients with mild to moderate impairment of liver or kidney function do not usually need to have their dosage adjusted. Patients with severe impairment of liver or kidney function should not exceed a daily dose of 10 mg.

Use in elderly patients

The dosage does not need to be adjusted.

Use in children and adolescents

Bisoprolol Fumarate Inovamed is not intended for use in children and adolescents, as its efficacy and safety have not been evaluated in this age group.

Do not exceed the recommended dose.

Treatment with Bisoprolol Fumarate Inovamed is usually long-term.

Crushing/halving/chewing:

Do not crush or chew the tablet. It is possible to halve the table and to take half a dose as needed.

If you accidentally take too high a dose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room, and bring the package of the medicine with you.

The signs of having taken an overdose of Bisoprolol Fumarate Inovamed may include a slowed heart rate, severe breathing difficulties, dizziness or tremor (due to decreased blood sugar).

If you forgot to take the medicine at the designated time, do not under any circumstances take a double dose to make up for the single forgotten dose. Take your usual dose the next morning.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not alter or stop treatment with Bisoprolol Fumarate Inovamed without consulting with the doctor. Otherwise, your condition may become worse.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Bisoprolol Fumarate Inovamed may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

To prevent serious reactions, speak to a doctor immediately if a side effect is severe, occurs suddenly or gets worse rapidly.

The most severe side effects are related to heart function:

- Slowing of heart rate (may affect more than 1 in 10 patients)
- Worsening of heart failure (may affect up to 1 in 10 patients)
- Slow or irregular heartbeat (may affect up to 1 in 100 patients)

If you experience dizziness, weakness or breathing difficulties – contact a doctor as soon as possible.

Additional side effects:

Common side effects – effects that occur in 1-10 in 100 users:

- Tiredness, weakness, dizziness, headache
- Low blood pressure
- Abdominal or intestinal problems such as nausea, diarrhea, vomiting, constipation
- Sensation of cold or loss of sensation in hands or feet

Uncommon side effects – effects that occur in 1-10 in 1,000 users:

- Breathing problems in patients with asthma or chronic lung diseases
- Muscle weakness, muscle spasms
- Sleep disturbances
- Depression
- Dizziness upon standing up

Rare side effects – effects that occur in 1-10 in 10,000 users:

- Certain liver function or fat level blood test results differing from normal
- Inflammation of the liver, which can cause yellowing of the skin or of the whites of the eyes
- Fainting
- Reduced secretion of tears
- Hearing disturbances

- Allergic runny nose
- Allergy-like reactions such as itching, redness, rash. You should see a doctor straight away if you experience more severe allergic reactions, which may involve face, neck, tongue or throat swelling, or difficulty breathing
- Erection problems
- Nightmares, hallucinations

Very rare side effects – effects that occur in less than 1 user in 10,000:

- Irritation and redness of the eye (conjunctivitis)
- Hair loss
- Appearance or worsening of scaly skin rash (psoriasis), psoriasis-like skin rash.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.
- Store in the original package in order to protect from light.
- For the bottle package (plastic container) – shelf life after first opening the 30-tablet bottle: May be used for 45 days, but not after the medicine's expiry date.
- Do not store different medicines in the same package.
- Do not throw away this medicinal product in the household trash. Ask your pharmacist how to dispose of medicinal products that are no longer needed. You will thus be able to contribute to the protection of the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains the following inactive ingredients:

Calcium Hydrogen Phosphate Anhydrous, Cellulose Microcrystalline (PH-112), Silica Colloidal Anhydrous, Crospovidone (type-A), Magnesium Stearate, Hypromellose 6cP, Titanium Dioxide (E171), Macrogol 400.

What the medicine looks like and the contents of the package:

Bisoprolol Fumarate Inovamed 2.5 mg tablets: The medicine appears as a white, circular, biconvex film-coated tablet, debossed with the letter 'P' and a break line on one side and the number '2' on the other side.

Bisoprolol Fumarate Inovamed 5 mg tablets: The medicine appears as a white, circular, biconvex film-coated tablet, debossed with the letter 'P' and a break line on one side and the number '5' on the other side.

Bisoprolol Fumarate Inovamed 10 mg tablets: The medicine appears as a white, circular, biconvex film-coated tablet, debossed with the letter 'P' and a break line on one side and the number '10' on the other side.

The tablets are packaged in plastic trays (blisters), which are packaged in carton boxes or plastic boxes.

Package size: The medicine is supplied in two package types, as detailed:

- Carton packages containing plastic tray/s with 7, 10, 14, 20, 28, 30, 50, 56, 60, 90, 100 or 300 tablets. The number of blister packs in a package may vary depending on the package size. The number of tablets in each package appears on the carton package.
- Bottle packages (plastic containers), closed with a screw cap, with 30 tablets.

Not all package sizes may be marketed.

Registration holder and address: Inovamed Ltd., 55 Beer Ganim St., P.O.B. 62, Even Yehuda 40500, Israel.

Manufacturer and address: Aurobindo Pharma Ltd., Mairivihar 2, Ameerpet, Hyderabad, India.

Revised in July 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Bisoprolol Fumarate Inovamed 2.5 mg:

152.66.34099

Bisoprolol Fumarate Inovamed 5 mg:

152.67.34098

Bisoprolol Fumarate Inovamed 10 mg:

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