

# PRIVANTA FILM-COATED TABLET

Bisoprolol fumarate (2.5 mg, 5 mg and 10 mg)

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## What Privanta is used for

Privanta 2.5 mg is used to treat chronic stable heart failure.

Privanta 5 mg and 10 mg is used to treat high blood pressure, angina pectoris and chronic stable heart failure.

## How Privanta works

The active substance in Privanta is bisoprolol. Bisoprolol belongs to a group of medicines called beta-blockers. These medicines work by affecting the body's response to some nerve impulses, especially in the heart. As a result, bisoprolol slows down the heart rate and makes the heart more efficient at pumping blood around the body.

Heart failure occurs when the heart muscle is weak and unable to pump enough blood to supply the body's needs. Heart failure may begin with no symptoms, but as the condition progresses, you may feel shortness of breath. You may experience palpitations (initially during ordinary exercise, but later on also at rest), feel tired, and notice swelling of the feet and ankles due to fluid buildup.

## Before you use Privanta

### -When you must not take it

Do not take Privanta if one of the following conditions applies to you:

- allergy (hypersensitivity) to bisoprolol or to any of the other ingredients.
- severe asthma or severe chronic obstructive airway disease.
- severe blood circulation problems in your limbs (such as Raynaud's syndrome), which may cause your fingers and toes to tingle or turn pale or blue.
- untreated phaeochromocytoma, which is a rare tumour of the adrenal gland.
- metabolic acidosis, which is a condition when there is too much acid in the blood.

Do not take Privanta if you have one of the following heart problems:

- acute heart failure, that is not controlled medically.
- worsening heart failure requiring injection of medicines into a vein, that increase the force of contraction of the heart.
- slow heart rate that causes problems.
- low blood pressure that causes problems.
- certain heart conditions causing a very slow heart rate or irregular heartbeat (second- or third-degree AV-block, sinoatrial block, sick sinus syndrome).
- cardiogenic shock, which is an acute serious heart condition causing low blood pressure and circulatory failure.

### -Before you start use it

If you have any of the following conditions, tell your doctor before taking Privanta; he or she may want to take special care (for example give additional treatment or perform more frequent checks):

- diabetes.
- strict fasting.
- certain heart diseases (such as disturbances in heart rhythm or Prinzmetal's angina).
- kidney or liver problems.
- less severe blood circulation problems in your limbs
- less severe chronic bronchial diseases (asthma or chronic obstructive airway disease).
- history of scaly skin rash (psoriasis).
- tumour of the adrenal gland (phaeochromocytoma).
- thyroid disorder.

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

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

### -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.

Do not take the following medicines with Privanta without special advice from your doctor:

- Class I antiarrhythmic medicines (such as quinidine, disopyramide,

lidocaine, phenytoin, flecainide, propafenone). These medicines are used to treat irregular or abnormal heartbeat.

- Certain calcium antagonists used to treat high blood pressure, angina pectoris or irregular heartbeat such as verapamil and diltiazem.
- Certain medicines used to treat high blood pressure such as clonidine, methyl dopa, moxonidine and rilmenidine.

However, do not stop taking these medicines without checking with your doctor first.

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

- Certain calcium antagonists used to treat high blood pressure or angina pectoris such as felodipine and amlodipine (dihydropyridine type antagonists).
- Class III antiarrhythmic medicines (such as amiodarone). These medicines are used to treat irregular or abnormal heartbeat.
- Beta-blockers applied locally (such as eyedrops for glaucoma treatment).
- Nervous system medicines which are used to stimulate the inner organs or treat glaucoma (parasympathomimetic) or are used in emergency setting to treat severe circulatory conditions (sympathomimetics).
- Antidiabetic medicines including insulin.
- Anaesthetic agents (for example during surgery).
- Digitalis, used to treat heart failure.
- Non-steroidal anti-inflammatory medicines (NSAIDs) used to treat arthritis, pain or inflammation (for example ibuprofen or diclofenac)
- Any medicine, which can lower blood pressure as a desired or undesired effect (such as tricyclic antidepressants, barbiturates, phenothiazines). Mefloquine, used for prevention or treatment of malaria.
- Monoamine oxidase inhibitors (except MAO-B inhibitors).

## How to use Privanta

### -How much to use

#### -Adults and elderly

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

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Treatment of hypertension or angina pectoris:

For both indications the usual dosage is one tablet Privanta 5 mg or ½ tablet Privanta 10 mg (equivalent to 5 mg bisoprolol fumarate) once daily.

If necessary, the dose may be increased to one tablet Privanta 10 mg or 2 tablets Privanta 5 mg (equivalent to 10 mg bisoprolol fumarate) once daily.

The maximum recommended dose is 20 mg bisoprolol fumarate once daily.

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

Treatment of chronic heart failure:  
Treatment with bisoprolol 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 one week.
- 2.5 mg bisoprolol fumarate once daily for one week.
- 3.75 mg bisoprolol fumarate once daily for one week.
- 5 mg bisoprolol fumarate for four weeks.
- 7.5 mg bisoprolol fumarate once daily for four weeks.
- 10 mg bisoprolol fumarate once daily for maintenance (on-going) therapy.

Depending on how well you tolerate the medicine, your doctor may also decide to lengthen the time between dose increases.

If your condition gets worse or you no longer tolerate the drug, it may be necessary to reduce the dose again or to interrupt treatment. In some patients a maintenance dose lower than 10 mg bisoprolol fumarate may be sufficient. Your doctor will tell you what to do. The maximum recommended daily dose is 10 mg bisoprolol fumarate for chronic stable heart failure and 20 mg bisoprolol fumarate for high blood pressure and angina pectoris.

Elderly: No dose adjustment is required in the elderly.

Children: Privanta is not recommended for use in children.

#### -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

Treatment with Privanta is usually long-term.

#### -If you forget to use it

Do not take a double dose to make up for a forgotten dose. Take your usual dose the next morning.

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

If you have taken more Privanta tablets than you should, tell your doctor immediately. Your doctor will decide what measures are necessary.

Symptoms of an overdose may include slowed heart rate (bradycardia), acute narrowing of the airways leading to difficulty in breathing (bronchospasm), marked drop in blood pressure, acute heart failure, or a decrease in blood sugar.

Never stop taking Privanta unless on your doctor's advice. Otherwise, your condition could become much worse. If you have to stop treatment, your doctor will usually advise you to reduce the dose gradually.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### **While you are using Privanta**

##### -Things you must do

If you are pregnant or planning to become pregnant, tell your doctor. He or she will decide whether you can take Privanta during pregnancy.

It is not known whether bisoprolol passes into human breast milk. Therefore, breastfeeding is not recommended during therapy with Privanta

##### -Things you must not do

Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to. Do not give this medicine to anyone else, even if they have the same condition as you. Do not stop taking Privanta or change the dosage, without checking with your doctor.

#### -Things to be careful of

Your ability to drive or use machines may be affected depending on your tolerance to the medication. Please be careful, especially at the beginning of treatment, when the dose is increased or when the drug is changed or when taken with alcohol.

#### **Side effects**

Like all medicines, Privanta can cause side effects, although not everybody gets them. These side effects are listed below according to how frequently they may occur:

Very common (affect more than 1 person in 10):

- Slowing of heart rate (bradycardia) especially in patients with chronic heart failure.

Common (affects less than 1 person in 10)

- Tiredness, dizziness, headache.
- Feeling weak especially in patients with chronic heart failure.
- Feeling of coldness or numbness in hands or feet.
- Low blood pressure especially in patients with chronic heart failure.
- Worsening of heart failure especially in patients with chronic heart failure.
- Stomach or intestine problems such as nausea, vomiting, diarrhoea or constipation. Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

#### **Storage and Disposal of Privanta- Storage**

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not use Privanta after the expiry date which is stated on the blister and the carton after EXP.

#### -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.

# PRIVANTA FILM-COATED TABLET

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## Product Description

### -What it looks like

*Privanta Film-Coated Tablet 2.5 mg:*

White, heart shaped, biconvex film-coated tablet, scored on both sides.

*Privanta Film-Coated Tablet 5 mg:*

Light yellow, heart shaped, biconvex film-coated tablet, scored on both sides.

*Privanta Film-Coated Tablet 10 mg:*

Light orange, heart shaped, biconvex film-coated tablet, scored on both sides.

### -Ingredients

#### **Privanta Film-Coated Tablet 2.5mg**

##### *-Active ingredient*

Bisoprolol fumarate

##### *-Inactive ingredient*

Calcium Hydrogen Phosphate Anhydrous, Microcrystalline Cellulose, Crospovidone Micronized, Magnesium Stearate, Opadry white and purified water.

#### **Privanta Film-Coated Tablet 5mg**

##### *-Active ingredient*

Bisoprolol fumarate

##### *-Inactive ingredient*

Calcium Hydrogen Phosphate Anhydrous, Microcrystalline Cellulose, Crospovidone Micronized, Magnesium Stearate, Opadry yellow and purified water.

#### **Privanta Film-Coated Tablet 10mg**

##### *-Active ingredient*

Bisoprolol fumarate

##### *-Inactive ingredient*

Calcium Hydrogen Phosphate Anhydrous, Microcrystalline Cellulose, Crospovidone Micronized, Magnesium Stearate, Opadry yellow and purified water.

### -MAL number

#### **Privanta Film-Coated Tablet 2.5 mg:**

MALxxxxxxx

#### **Privanta Film-Coated Tablet 5 mg:**

MALxxxxxxx

#### **Privanta Film-Coated Tablet 10 mg:**

MAL21106021AZ

## **Product Registration Holder & Manufacturer**

Pharmaniaga Manufacturing Berhad  
(198001006232)

No 11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.