

**Bisoprolol Fumarate and
Hydrochlorothiazide Tablets
USP 2.5mg/6.25mg,
5mg/6.25mg, 10mg/6.25mg,
5mg/12.5mg Taj Pharma**

**Bisoprolol Fumarate and
Hydrochlorothiazide Tablets**

Package leaflet: Information for the user

**Read all of this leaflet carefully before you
start using this medicine.**

Keep this leaflet. You may need to read it again.

- If you have any further questions, ask
your doctor or pharmacist.

- This medicine has been prescribed for
you. Do not pass it on to others. It may harm
them, even if their symptoms are the same as
yours.

If you get any side effects, atlk to your doctor or
pharmacist. This includes any possibel side
effects not liseted in this leaflet.

In this leaflet:

1. What Bisoprolol Fumarate and
Hydrochlorothiazide is and what it is used for
2. What you need to know before you take
Bisoprolol Fumarate and Hydrochlorothiazide
3. How to take Bisoprolol Fumarate and
Hydrochlorothiazide
4. Possible side effects
5. How to store Bisoprolol Fumarate and
Hydrochlorothiazide

6. Contents of the pack and other information

**1. What Bisoprolol Fumarate
and Hydrochlorothiazide is and
what it is used for**

BISOPROLOL / HYDROCHLOROTHIAZIDE
contains the active substances bisoprolol and
hydrochlorothiazide:

- Bisoprolol belongs to a group of
medicines called beta-blockers and is
used to lower blood pressure.
- Hydrochlorothiazide belongs to a group
of medicines called thiazide diuretics
("water tablets") and also helps to lower
blood pressure by increasing urine
output.

This medicine is used to treat mild to moderate
high blood pressure.

**2. What you need to know
before you take Bisoprolol
Fumarate and
Hydrochlorothiazide**

**Do not take BISOPROLOL /
HYDROCHLOROTHIAZIDE**

Do not take BISOPROLOL /
HYDROCHLOROTHIAZIDE if one of the
following conditions applies to you:

- Allergy (hypersensitivity) to bisoprolol,
hydrochlorothiazide, other thiazides,
sulphonamides, or to any of the other
ingredients (see section 6 'What
BISOPROLOL /
HYDROCHLOROTHIAZIDE contains'),
- Severe asthma or certain severe forms of
chronic bronchial diseases,
- Heart failure not controlled by therapy, or
cardigenic shock (an acute serious heart

- condition causing low blood pressure and circulatory failure),
- Certain cardiac rhythm disorders, in particular slow heart rate causing problems, conduction disturbances or a disorder called sick sinus syndrome,
 - Untreated phaeochromocytoma (tumour of the adrenal gland secreting substances which induce severe high blood pressure),
 - Severe blood circulation problems in your limbs (such as Raynaud's syndrome which may cause your fingers or toes to tingle or turn pale or blue),
 - Increased blood acidity (metabolic acidosis) as a result of severe illness,
 - Severe liver or kidney problems,
 - Low blood levels of potassium, not responding to treatment,
 - If you are taking sultopride (which is used to treat certain psychiatric disorders).

Warning and precautions

Never suddenly stop taking treatment, in particular if you suffer from certain heart disorders (ischaemic heart disease, for example angina pectoris).

Talk to your doctor before taking **BISOPROLOL / HYDROCHLOROTHIAZIDE** if you have:

- Any heart disease such as heart failure, disturbances in heart rhythm, or Prinzmetal's angina,
- Less severe blood circulation problems in your limbs (in particular Raynaud's syndrome),
- Kidney or liver problems,
- Phaeochromocytoma (tumour of the adrenal gland),
- Less severe chronic bronchial disease (asthma or chronic obstructive airway disease),
- Diabetes,
- Thyroid disorders,
- Psoriasis,
- Strict fasting.

- If you have ever suffered from gout, as **BISOPROLOL / HYDROCHLOROTHIAZIDE** may enhance the risk for gout attacks,
- If you are going to have an anaesthetic (g. For surgery) because **BISOPROLOL / HYDROCHLOROTHIAZIDE** may influence how your body reacts to this situation,
- If you plan to have desensitisation therapy, because **BISOPROLOL / HYDROCHLOROTHIAZIDE** may make it more likely that you experience an allergic reaction, or that such a reaction may be more severe,
- If you are breast-feeding or intend to do so,
- If you intend to expose yourself to the sun or to artificial UV light, as a few patients have experienced skin rash after exposure to sunlight. In this case, you should protect your skin while you are treated with **BISOPROLOL / HYDROCHLOROTHIAZIDE**.

Hydrochlorothiazide works by influencing the salt and water balance in your body. Your doctor may want to check this from time to time. This is especially important if you have additional conditions which may become worse if the electrolyte balance is disturbed. Your doctor will also check your levels of blood fats, uric acid, or blood glucose from time to time.

This medicine is not recommended at the same time as lithium (used to treat some psychiatric disorders) or medicines used to treat high blood pressure, angina pectoris or irregular heart beat (such as verapamil, diltiazem or bepridil) (see section "Taking other medicines").

Competitive athletes should be aware that this product contains an active substance that may give a positive reaction in doping tests.

Other medicines and Bisoprolol/Hydrochlorothiazide

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

You must not take Bisoprolol/Hydrochlorothiazide if you are treated with the following medicine (see above, “Do not take Bisoprolol/Hydrochlorothiazide”):

Especially talk to your doctor if you are taking one of the following:

- Antiarrhythmic drugs (such as diltiazem, verapamil, bepridil, propafenone, cibenzoline, flecainide, lidocaine, amiodarone, sotalol)
- Certain psychiatric drugs (lithium, pimozone, haloperidol, sulpiride)
- Any antihypertensive drugs (e.g. Clonidine, methyldopa, moxonidine, rilmenidine, nifedipine, amlodipine, so called ACE inhibitors (e.g. Ramipril, perindopril, trandalopril, perindopril etc.), so called angiotensin II receptor antagonists (e.g. Valsartan, olmesartan, losartan etc.)
- Antidiuretics (such as amiloride, triamterene, spironolactone),
- Certain allergy drugs (astemizole and terfenadine)
- Bepridil (drug for angina pectoris),
- Certain drugs for stomach problems (cisapride and diphemanil)
- Certain antibiotics (erythromycin, moxifloxacin, pentamidine, spiramycin, sparfloxacin, and amphotericin)
- Certain drugs for malaria (halofantrine, lumefantrine and mefloquine)
- Methadone,
- Vincamine,
- Donepezil (drug for Alzheimer disease),
- Drugs for a disease called miastenia gravis (e.g. neostigmin)
- Drugs for the treatment of diabetes mellitus (insulin, sulphonylureas, glinides)
- Digitalis (digoxin)(drug for heart failure)

- Pain killers such as ibuprofen, acetylsalicylic acid, diclofenac, naproxen (so called non-steroidal antiinflammatory drugs)
- Laxatives
- Drugs for gout (e.g. Alopurinol)
- Eye drops for glaucoma treatment (e.g. Timolol)
- Carbamazepine (a drug for epilepsy and pain)
- Calcium
- Ciclosporin
- Corticosteroids (e.g. Cortisone, prednisone, prednisolone)
- If you need a surgery under general anesthesia, the doctor must know you take Bisoprolol/ Hydrochlorothiazide

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, thing you might be pregnant or are planning to have a baby, ask your doctor or pharmacist before taking this medicine.

Usually, your doctor will advise you to take another medicine instead of BISOPROLOL / HYDROCHLOROTHIAZIDE , as it is not recommended during pregnancy. This is because hydrochlorothiazide crosses the placenta and its use after the third month of pregnancy may cause potentially harmful fetal and neonatal effects.

Use of this medicine is not recommended during breast-feeding.

Driving and using machines

Normally BISOPROLOL / HYDROCHLOROTHIAZIDE does not affect your ability to drive or use machines. However, your individual response may influence your ability to concentrate and react. If this happens, do not drive vehicles or use machines.

3. How to take Bisoprolol Fumarate and Hydrochlorothiazide

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

The usual starting dose is one 2.5 mg/6.25 mg tablet daily. If the blood pressure-lowering effect of this dose is inadequate, the dose will be increased to one 5 mg/6.25 mg tablet daily and, if the response is still inadequate, to one 10 mg/6.25 mg tablet daily.

Take BISOPROLOL / HYDROCHLOROTHIAZIDE in the morning, with or without food. Swallow the tablet with some liquid. Do not chew.

Never suddenly stop taking treatment (see section “If you stop taking BISOPROLOL / HYDROCHLOROTHIAZIDE”).

Children

There is no experience with BISOPROLOL / HYDROCHLOROTHIAZIDE in children, therefore its use is not recommended for children.

Taking BISOPROLOL / HYDROCHLOROTHIAZIDE with food and drink

BISOPROLOL / HYDROCHLOROTHIAZIDE may be taken with or without food, but must be taken in the morning.

If you take more BISOPROLOL / HYDROCHLOROTHIAZIDE than you should

If you have taken more BISOPROLOL / HYDROCHLOROTHIAZIDE tablets than you

should, inform your doctor immediately. Depending on the degree of overdose, your doctor can decide what measures are necessary.

Symptoms of an overdose may include low blood pressure, slow heartbeat, sudden heart problems, dizziness, nausea, sleepiness, sudden breathing problems, low blood sugar.

If you forget to take BISOPROLOL / HYDROCHLOROTHIAZIDE

If you forget to take this medicine, take it as soon as you remember. Then take your next dose at its usual time. However, if it is almost time for your next dose skip the dose you missed. Do not take a double dose to make up for a forgotten tablet.

If you stop taking BISOPROLOL / HYDROCHLOROTHIAZIDE

Never stop taking this medicine except 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.

4. Possible side effects

Like all medicines, Bisoprolol/Hydrochlorothiazide can cause side effects, although not everybody gets them.

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

Common side effects (affect less than 1 person in 10):

- Feeling of coldness or numbness in hands and feet
- Tiredness, dizziness, headache. These symptoms occur mainly at the beginning of the treatment. They are generally mild, and usually disappear within 1 to 2 weeks after starting the treatment
- Stomach or intestine problems such as nausea, vomiting, diarrhoea, or constipation.

Uncommon side effects (affect less than 1 person in 100):

- Muscular weakness, muscular cramps, feeling weak
- Slow heart beat, impaired heart rate, worsening of heart failure, drop in blood pressure after standing or sitting up
- Sleep disorders, depression, loss of appetite
- Breathing problems in patients with asthma or chronic bronchial disease
- Increase of blood-levels for creatinine or urea
- Abdominal complaints
- Increased amylase levels (enzymes involved in digestion),
- Disturbed balance of fluids and electrolytes
- Increased blood levels for fat, cholesterol, uric acid or sugar; increased urine levels for sugar

Rare side effects (affect less than 1 person in 1,000):

- Nightmares, hallucinations.
- Allergy-type reactions, such as itching, sudden flushing of the face or skin rash, also after exposure to sunlight, hives, small purple-red marks on the skin caused by bleeding under the skin (purpura),
- Increase in certain liver enzymes, inflammation of the liver, yellow colouring of skin and eyes (jaundice),
- Erection disorders,
 - Hearing problems,
 - Allergic runny nose, reduced tear secretion, visual disturbance,

- Decrease in number of white blood cells (leukocytopenia), or blood platelets (thrombocytopenia).

Very rare side effects (affect less than 1 person in 10,000):

- Irritation and redness of the eye (conjunctivitis), hair loss
- Onset or worsening of pre-existing scaly skin rash (psoriasis); onset of thick scaly patches (cutaneous lupus erythematosus)
- Chest pain
- Severe reduction in the number of white blood cells (agranulocytosis)
- Inflammation of the pancreas
- Condition of too little acid in your blood (metabolic alkalosis)
- Allergic (anaphylactic) reactions, severe bullous reactions (Lyell syndrome)

Tell your doctor if you notice any of the side effects listed above or any other unwanted or unexpected effects. To prevent serious reactions, speak to a doctor immediately if a side effect is severe, occurred suddenly or gets worse rapidly.

5. How to store Bisoprolol Fumarate and Hydrochlorthiazide

Store below 30°C. Store in the original package. Keep out of the reach and sight of children. Do not use Bisoprolol/Hydrochlorothiazide after the expiry date which is stated on the label. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information



What Bisoprolol / Hydrochlorothiazide contains

The active substances are bisoprolol fumarate and hydrochlorothiazide.

a) Each film-coated tablet contains:

Bisoprolol fumarate USP 2.5mg
Hydrochlorothiazide USP 6.25mg
Excipients: q.s.
Colours: Yellow Oxide of Iron and Titanium
Dioxide

b) Each film-coated tablet contains:

Bisoprolol fumarate USP 5mg
Hydrochlorothiazide USP 6.25mg
Excipients: q.s.
Colours: Yellow Oxide of Iron and Titanium
Dioxide

c) Each film-coated tablet contains:

Bisoprolol fumarate USP 10mg
Hydrochlorothiazide USP 6.25mg
Excipients: q.s.
Colours: Yellow Oxide of Iron and Titanium
Dioxide

d) Each film-coated tablet contains:

Bisoprolol fumarate USP 5mg
Hydrochlorothiazide USP 12.5mg
Excipients: q.s.
Colours: Yellow Oxide of Iron and Titanium
Dioxide

Pack Size: 7, 14, 28, 30, 50, 100 and 500
Tablets.

7. Manufactured in India by:

TAJ PHARMACEUTICALS LTD.

Mumbai, India

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