
PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION


Rx BISOPROLOL FUMARATE AND **5.0 /12.50**
HYDROCHLOROTHIAZIDE TABLETS USP

(bisoprolol fumarate + hydrochlorothiazide)

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Rx BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE TABLETS USP **5.0 /12.50**
(bisoprolol fumarate + hydrochlorothiazide)

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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- 1 What BISOPROLOL / HYDROCHLOROTHIAZIDE is and what it is used for**
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1 WHAT BISOPROLOL / HYDROCHLOROTHIAZIDE IS AND WHAT IT IS USED FOR

Bisoprolol belongs to a group of medicines called beta-blockers and is used to lower blood pressure.

Hydrochlorothiazide belongs to a group of drugs called thiazide diuretics ("water tablets") and also helps to

lower blood pressure by increasing urine output.

This medicine is indicated in the treatment of mild to moderate high blood pressure.

2 BEFORE YOU TAKE BISOPROLOL / HYDROCHLOROTHIAZIDE

Do not take Bisoprolol / HYDROCHLOROTHIAZIDE

- if you have heart failure not controlled by therapy,
- if you have certain cardiac rhythm disorders, in particular severe bradycardia (pulse rate below 50 beats per minutes), conduction disturbances or a disorder called sick sinus syndrome,
- if you have severe asthma and certain severe chronic bronchial diseases,
- if you have Prinzmetal angina (type of attack of angina pectoris),
- if you have untreated pheochromocytoma (tumour of the adrenal gland secreting substances which induce

severe high blood pressure),

- if you have peripheral arterial disorders (in particular Raynaud's syndrome) in their severe forms,

- if you have hypotension,

- if you are allergic (hypersensitive) to bisoprolol, to hydrochlorothiazide or to other sulphonamide derivatives,

- if you have severe impairment of renal or hepatic (liver) function,

- if you are taking floctafenine, which is used to treat some forms of arthritis, or sultopride, which is used to

treat some forms of psychiatric disorders (see 'Taking other medicines', below),

- if you are breastfeeding.

This medicine is generally not recommended in combination with lithium, which is used to treat some forms of

psychiatric disorders, or with certain medicines which increase the risk of heart rhythm disorders (see 'Taking other medicines').

Take special care with Bisoprolol / Hydrochlorothiazide

- Never suddenly stop taking treatment, in particular if you suffer from certain heart disorders (ischaemic heart

disease, for example angina pectoris).

Inform your doctor before taking the treatment in the following cases:

- If you suffer from heart disease,

- If you suffer from arterial diseases (in particular Raynaud's syndrome), pil-FR307-D210 2

- If you have a history of chronic airway disease, such as emphysema or bronchitis,

- If you suffer from diabetes, thyroid disorders, gout, psoriasis or kidney impairment or liver impairment,

- If you are undergoing desensitisation treatment,

- If you must undergo a surgical operation, tell the anaesthetist that you are taking this drug.

This medicine should be used with caution in the elderly.

Additional tests

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.

The attention of athletes is drawn to the fact that this drug contains an active substance that may give a positive

reaction in doping tests.

Taking other medicines

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 medicines (see

above, "Do not take Bisoprolol/Hydrochlorothiazide "):

- floctafenine, which is used to treat some forms of arthritis,

- sultopride, which is used to treat some forms of psychiatric

Continued top of next column

disorders.

You must only take Bisoprolol/Hydrochlorothiazide with the following medicines if your doctor has advised

you to do so, as it is generally not recommended to take these medicines at the same time (see above, "Do not

take Bisoprolol/Hydrochlorothiazide "):

- lithium, which is used to treat some forms of psychiatric disorders,

- certain medicines which may increase the risk of heart rhythm disorders such as:

- amiodarone, which is used to treat disturbances of heart rhythm,

- bepridil, which is used to treat angina pectoris,

- sparfloxacin or intravenous erythromycin, which are antibiotics

- pentamidine, which is used to treat parasite infestations,

- halofantrine, which is used to treat malaria,

- vincamine, which is used to treat certain forms of brain disease

- astemizole or terfenadine, which are antihistamines used to treat hives and hay fever.

Pregnancy and breast-feeding

Use of this medicine is not recommended during pregnancy.

Breast-feeding is contra-indicated.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Taking into account the risks of hypotension and dizziness, treatment with Bisoprolol / Hydrochlorothiazide

may compromise the ability to drive vehicles or use machines.

3 HOW TO TAKE BISOPROLOL / 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 doses are given below.

The dose is adapted to each patient.

The usual dosage is 1 tablet per day. Always take your medicine as instructed by your doctor.

If you have the impression that the effect of Bisoprolol/Hydrochlorothiazide 5 mg/12.5 mg, film-coated tablet is too weak or too strong, talk to your doctor or pharmacist.

Oral route.

The tablets should be taken in the morning, before, during or after breakfast. They should be swallowed with a little liquid and should not be chewed.

Bisoprolol / Hydrochlorothiazide should be administered once daily. pil-FR307-D210 3

If you take more Bisoprolol / Hydrochlorothiazide than you should

Consult your doctor or pharmacist immediately.

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If you forget to take Bisoprolol / Hydrochlorothiazide

If you forget to take your 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 dose.

If you stop taking Bisoprolol / Hydrochlorothiazide

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

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.

The most common side effects, which occur in more than 1 out of 100 patients and fewer than 1 out of 10

patients, are as follows:

- Feeling of coldness or numbness in the hands and feet,
- Tiredness*, exhaustion*, dizziness*, headaches*,
- Nausea, vomiting, diarrhoea or constipation,
- Abnormal laboratory test results, increased risk of gout.

* These symptoms occur in particular at the start of treatment.

Uncommon (more than 1 out of 1000 patients and fewer than 1 out of 100 patients):

- Muscular weakness and cramps,
- Slowing of heart rate, heart conduction disturbances, worsening of heart failure, orthostatic hypotension (fall in blood pressure on standing up which may be accompanied by dizziness),
- Sleep disorders, depression.
- Difficulties in breathing in patients with asthma or a history of obstructive airway disorders such as emphysema or bronchitis,
- Disturbances of kidney function,
- Loss of appetite, abdominal pain, increase in amylases (enzymes involved in digestion).

Rare (more than 1 out of 10000 patients and fewer than 1 out of 1000 patients):

- Nightmares, hallucinations,
- Allergic reactions such as itching, sudden redness of the face or skin rash, in particular after exposure to the sun,
- Increase in certain liver enzymes, hepatitis, jaundice,
- Erection disorders,
- Hearing disorders,
- Allergic rhinitis, reduced secretion of tears, visual disorders,
- Reduction in the number of white blood cells in the blood, reduction in the number of blood platelets which are involved in clotting.

Very rare (fewer than 1 out of 10000 patients):

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- Conjunctivitis, loss of hair on the head or body, worsening of psoriasis (skin disease) or occurrence of a

psoriasis-like rash or cutaneous lupus erythematosus (skin disease),

- Chest pain,

- Agranulocytosis (disappearance of certain types of white blood cells in the blood),

- Pancreatitis (inflammation of the pancreas which causes severe pain in the abdomen and back).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your

doctor or pharmacist.

5 HOW TO STORE BISOPROLOL / HYDROCHLOROTHIAZIDE

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. pil-FR307-D210 4

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 FURTHER INFORMATION

What BISOPROLOL / HYDROCHLOROTHIAZIDE contains

- The active substances are bisoprolol fumarate and hydrochlorothiazide.

[2.5 / 6.25 mg]

- Each tablet contains 2.5 mg bisoprolol fumarate and 6.25 mg hydrochlorothiazide.

[5 / 6.25 mg]

- Each tablet contains 5 mg bisoprolol fumarate and 6.25 mg hydrochlorothiazide.

[10 / 6.25 mg]

- Each tablet contains 10 mg bisoprolol fumarate and 6.25 mg hydrochlorothiazide.

- The other ingredients are:

All strengths:

Tablet core: maize starch, microcrystalline cellulose, colloidal anhydrous silica, anhydrous calcium hydrogen

phosphate, magnesium stearate

Film-coat: hypromellose, polysorbate 80, macrogol 400 and titanium dioxide E171,

[2.5 / 6.25 mg]: iron oxide yellow, red and black E172

[5 / 6.25 mg]: talc, iron oxide yellow, red and black E172.

What BISOPROLOL / HYDROCHLOROTHIAZIDE look like and contents of the pack:

[2.5 / 6.25 mg]

Your tablets are yellow, film coated round tablets, debossed with "2.5" on one side of the tablet and "BH" on the

other side of the tablet. They are available in packs of blisters containing 14, 28, 30, 56, 60 and 100 tablets.

[5 / 6.25 mg]

Your tablets are pink, film coated, round tablet, debossed with

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"5" on one side of the tablet and "BH" on the

other side of the tablets. They are available in packs of blisters containing 14, 28, 30, 56, 60 and 100 tablets.

[10 / 6.25 mg]

Your tablets are white, film coated, round tablet, debossed with "10" on one side of the tablet and "BH" on the

other side of the tablets. They are available in packs of blisters containing 14, 28, 30, 56, 60 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Manufactured in India by:

TAJ PHARMACEUTICALS LTD.

Mumbai, India

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BISOPROLOL AND HYDROCHLOROTHIAZIDE (ORAL ROUTE)

Bisoprolol and hydrochlorothiazide combination is used to treat high blood pressure (hypertension). High blood pressure adds to the workload of the heart and arteries.

If it continues for a long time, the heart and arteries may not function properly. This can damage the blood vessels of the brain, heart, and kidneys, resulting in a stroke, heart failure, or kidney failure. High blood pressure may also increase the risk of heart attacks. These problems may be less likely to occur if blood pressure is controlled.


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