Bisoprolol Fumarate and Amlodipine Besylate Tablets 5mg/5mg Taj Pharma

(Bisoprolol Fumarate and Amlodipine Besylate)

Package leaflet: Information for the user

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Bisoprolol Fumarate and Amlodipine Besylate is and what it is used for

Bisoprolol Fumarate and Amlodipine Besylate is indicated for the treatment of high blood pressure as substitution therapy in patients who are adequately controlled with the individual products given concurrently at the same doses level as in the combination, but as separate tablets.

2. What you need to know before you take Bisoprolol Fumarate and Amlodipine Besylate

Do not take Bisoprolol Fumarate and Amlodipine Besylate

- If you are allergic to amlodipine, bisoprolol (active substances), dihydropyridinederivates or any of the other ingredients of this medicine (listed in section 6);
- If you have serious narrowing of the outflow tract of the left ventricle (e.g. high grade aortic stenosis);
- If you suffer from acute heart failure, unstable heart failure after acute myocardial infarction or heart failure requiring intravenous drugs to increase strength of myocardial contraction;
- If you suffer from shock due to abnormal function of heart (in such cases blood pressure is extremly low and circulation is close to collapse);
- If you suffer from heart disease characterized by very slow heart beat or irregular heart contraction (2^{nd} or 3^{rd} degree atrioventricular block, sinoatrial block, sick sinus syndrome);
- In case of extremly low blood pressure (first value is permanently less than 100 mmHg);
- In case of severe bronchial asthma or chronic obstructive pulmonary disease;
- In case of serious peripheral arterial disease;
- In case of Raynaud syndrome, which is characterized by numbness, buzz and decoloration of fingers on hands and feet exposed to cold.
- In case of untreated pheocromocytoma, which is a rare tumour of adrenal glands' marrow;
- In such metabolic conditions where pH of blood becomes acidic

If you think you suffer from any of the above mentioned diseases, ask your doctor whether you can take the preparation.

Warnings and precautions
Bisoprolol Fumarate and Amlodipine Besylate can be administered with special care in the following conditions, therefore inform your doctor if any of the following conditions applies to you:

- Elderly age;
- Heart failure;
- Diabetes with highly variable blood sugar levels;
- Strict diet;
- Concomittant antiallergic (desensitizing) treatment (e.g. in order to prevent allergic rhinitis);
- Mild disorder of electronic regulatory system of heart rhythm (first degree AV-block);
- Coronary perfusion disorder (Prinzmetal's angina)
- Vascular disease of extremities characterized by decreased perfusion;
- Psoriasis;
- Hyperthyreosis;
- Hepatic or renal disease;
- In case of treated pheocromocytoma, which is a rare tumour of adrenal glands' marrow;
- Bronchial asthma or other chronic obstructive lung disease;
- If you are going to have an operation inform your anaesthetist, that you are taking Bisoprolol Fumarate and Amlodipine Besylate.

Your doctor may feel it necessary to take special measures (e.g. additional treatment), if any of the above conditions exists.

Children and adolescents
Do not give this medicine to children or adolescents below the age of 18, because its benefits and risks have not been tested in these age groups.

Other medicines and Bisoprolol Fumarate and Amlodipine Besylate
Therapeutic and side effects of this medicine may be biased by other medicines being concomitantly taken.
Interactions can arise, even if other medicine has been taken within just short time.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

<u>The coadministration of the following medicines with Bisoprolol Fumarate and Amlodipine Besylate is not recommended:</u>

Verapamil- and diltiazem type calcium channel blockers: These drugs are used for the treatment of high blood pressure and chronic stable angina pectoris.

Centrally acting antihypertensives (e.g.: clonidine, methyldopa, moxonodine, rilmenidine): Do not stop taking these drugs before consulting your doctor.

<u>The following drugs may only be coadministered with Bisoprolol Fumarate and Amlodipine Besylate in certain circumstances with special caution under medical supervision:</u>

Certain heart rhythm regulator preparations (quinidine, disopyramide, lidocaine, phenytoin, flecainide, propaphenon, amiodarone). These drugs are used for the treatment of irregular or abnormal heart rhythm.

Topically applied beta-blocker preparations (e.g. eye-drops used to treat glaucoma).

Parasympathomimetics. These drugs are used to potentiate function of smooth muscle in diseases of stomach, intestinum, bladder and in glaucoma.

Insulin and oral antidiabetics. Hypnotics, anaesthetic agents.

Heart glycosides (digitalis), drugs used to treat heart failure.

Non steroidal antiinflammatory drugs (NSAIDs). These drugs may be given for the treatment of joint inflammation, pain or arthritis.

Sympathomimetics (e.g. isoprenalin, dobutamine, norepinephrine, epinephrin). These drugs are used for the treatment of serious circulation disorders in case of emergence.

Any drugs lowering blood pressure due to therapeutic or adverse effect (e.g. antihypertensive medicines, tricyclic antidepressants, barbiturates, phenothiazines).

Simvastatin, a cholesterol lowering medicine.

Possible effects of a coadministration of the following medicines with Bisoprolol Fumarate and Amlodipine Besylate need to be considered by your doctor:

Mefloquine, used to prevent or treat malaria.

Monoamino-oxidase (MAO) inhibitors (except MAO-B inhibitors) used to treat depression.

Drugs affecting metabolism of amlodipine or bisoprolol (e.g. rifampicine, ketoconazole, itraconazole, erythromycin, ritonavir, and St. John's wort).

Ergotamine derivates (drugs used to treat bleedings of gynaecological origin)

Bisoprolol Fumarate and Amlodipine Besylate with alcohol
Alcohol may potentiate blood pressure lowering effect of the preparation.

Pregnancy and breast-feeding

Pregnancy
As no appropriate amount of clinical experience is available concerning pregnant women, it can be administered only after careful individual consideration of risk/benefit ratio by a doctor, therefore don't forget to inform your doctor if you may be pregnant or you plan to have a baby. In case of its administration in pregnancy, careful monitoring of foetus' and newborn's condition may be necessary.

Breast-feeding
Bisoprolol Fumarate and Amlodipine Besylate is not recommended during breast-feeding.

Driving and using machines

Bisoprolol Fumarate and Amlodipine Besylate may impair driving or using machines by causing dizziness, headache, fatigue or nausea – especially when you start treatment or if your treatment is changed, and when you drink alcohol – therefore your doctor decides individually at what kind of dosage you can drive or use machines.

3. How to take Bisoprolol Fumarate and Amlodipine Besylate

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The recommended dose is one tablet of the strength prescribed for you. Usually there is no need of dose adjustment in mild to moderate liver or kidney disease. In serious liver or kidney disease doses may be modified. Elderly

There is no need of dose adjustment in elderly patients, however, caution is advised when the dose is increased.

Method of administration
Bisoprolol Fumarate and Amlodipine Besylate should be taken in the morning, with or without food, with a little fluid without chewing it.
The score line is only there to help you break the tablet if you have difficulties swallowing it whole.

If you feel that the therapeutic effect of Bisoprolol Fumarate and Amlodipine Besylate is too strong or too weak, consult your doctor or pharmacist.

If you take more Bisoprolol Fumarate and Amlodipine Besylate than you should

If you take more Bisoprolol Fumarate and Amlodipine Besylate than you should, consult a doctor immediately.

If you forget to take Bisoprolol Fumarate and Amlodipine Besylate
Try to make up missed dose as soon as possible. If it is already time to take next dose, do not take a double dose to make up for a forgotten dose, because you cannot compensate missed amount but you expose yourself to the risk of overdose.

If you stop taking Bisoprolol Fumarate and Amlodipine Besylate
Do not stop taking drug abruptly, or change recommended dose before consulting your doctor, as in such cases heart failure may temporarily worsen. Treatment must not been discontinued abruptly especially in patients with coronary disease. If cessation of treatment is necessary, dose must be reduced gradually.

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

4. Possible side effects

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

Common: may affect up to 1 in 10 people
Headache, dizziness, somnolence (especially at the beginning of the treatment), palpitation, flush, abdominal pain, ankle swelling, oedema, fatigue, feeling of coldness and numbness in the extremities, gastrointestinal complaints such as nausea, vomiting, diarrhoea, constipation.

Uncommon: may affect up to 1 in 100 people
Insomnia, mood changes (including anxiety), depression, temporary loss of consciousness (syncope), hypaesthesia, paraesthesia, abnormal sense of taste (dysgeusia), tremor, visual disturbances (including diplopia), tinnitus, hypotension, dyspnoe, rhinitis, altered bowel habits (including diarrhoea and constipation), dyspepsia, dry mouth, alopecia, small bleedings in the skin and mucosa (purpura), skin discolouration, increased sweating, itching, rash, exanthema, arthralgia, myalgia, muscle cramps, back pain, frequent micturition, micturition disorder, nycturia, impotence, breast enlargement in men, chest pain, asthenia, pain, malaise, weight increase, weight decrease, sleep disorders, heart conduction disorders, deterioration of pre-existing heart failure, slow heart rate (less than 50 beat per minute), low blood pressure, bronchospasm in patients with bronchial asthma or a history of obstructive pulmonary disease, muscle weakness and cramps, exhaustion*.
*These symptoms especially occur at the beginning of the therapy. They are generally mild and often disappear within 1-2 weeks.

Rare: may affect up to 1 in 1,000 people
Confusion, elevated level of triglyceride, nightmares, sense illusion, which is an abnormal sensation without detectable stimulus, similar to real sensation and seems real (hallucination), decreased tear secretion (it must be taken into consideration if you wear contact lenses), hearing impairments, allergic rhinitis, hepatitis, hypersensitivity reactions such as itching, flush, rash, elevated liver enzymes.
Very rare: may affect up to 1 in 10,000 people
Decrease of number or white blood cells and platelets, allergic reactions, elevated level of blood sugar, hypertonia, peripheral neuropathy, heart attack, cardiac arrhythmia, patchy inflammation of small blood vessels (vasculitis), cough, gastritis, gingival hyperplasia, pancreatitis, jaundice, acute swelling of skin or mucosa involving most frequently eyelids, lips, joints, genitals, glottis, pharynx and tongue (angio-oedema), serious inflammation of skin or mucosa with red vesicles (erythema multiforme), urticaria, widespread erythema and scaling of the skin (exfoliative dermatitis), serious blistering lesions of the skin and mucous membranes of the mouth, genital and anal regions, with fever, sore throat and fatigue (Stevens-Johnson syndrome), sensitivity to the sunlight, conjunctivitis, drugs with similar mechanism of action than bisoprolol (active ingredient of the preparation) may evoke or

worsen psoriasis (chronic skin disease with itchy scaly red patches) or may cause psoriasis-like skin disorder, disorders combining involuntary movements, muscle rigidity and contractions, tremor (extrapyramidal syndrome).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Bisoprolol Fumarate and Amlodipine Besylate

Do not store above 30 C. Store in the original container in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton (year/month). The expiry date refers to the last day of that month.
Keep this medicine out of the sight and reach of children.

Do not use this medicine if you notice the visible signs (discoloration) of deterioration.

6. Contents of the pack and other information

What Bisoprolol Fumarate and Amlodipine Besylate contains

Each film coated tablet contains:

Bisoprolol Fumarate USP	5mg
Amlodipine Besylate USP Equivalent to Amlodipine base	5mg
Excipients	q.s.
Colour: Titanium Dioxide USP	

What Bisoprolol Fumarate and Amlodipine Besylate looks like and contents of the pack

Tablets are packed in OPA/Al/PVC//Al blister and carton box.

Pack Size: 7, 14, 28, 30, 50,90, 100 and 500 tablets.

Not all pack sizes may be marketed.

7. Manufactured In India By:
TAJ PHARMACEUTICALS LTD.
Mumbai, India
Unit No. 214.Old Bake House,
Maharashtra chambers of Commerce Lane,
Fort, Mumbai - 400001
at:Gujarat, INDIA.
Customer Service and Product Inquiries:
1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)
Monday through Saturday 9:00 a.m. to 7:00 p.m. EST
E-mail: tajgroup@tajpharma.com