

VASOTEN F.C. TABLETS 5MG

Bisoprolol fumarate

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What Vasoten F.C. Tablets 5mg is used for

The name of your medicine is Vasoten F.C. Tablets 5mg. It contains the active ingredient, Bisoprolol fumarate.

This medicine is used for management of hypertension and angina pectoris.

How Vasoten F.C. Tablets 5mg works

Bisoprolol is used with or without other medications to treat high blood pressure (hypertension).

This medication belongs to a class of drugs known as beta blockers. It works by blocking the action of certain natural chemicals in your body such as epinephrine on the heart and blood vessels. This effect lowers the heart rate, blood pressure, and strain on the heart.

Before you use Vasoten F.C. Tablets 5mg

When you must not take it

You should not use this medicine if you have had an allergic reaction to **bisoprolol** or any type of beta blocker medicine (such as atenolol, metoprolol, propranolol, Corgard®, Inderal®, Lopressor®, Tenormin®, or Toprol®), or if you have certain heart

problems. Talk with your doctor about what these heart problems are.

Do not use this medicine if you have severe asthma, hypotension, phaeochromocytoma and metabolic acidosis.

Before you start to take it

Talk with your doctor if you have:

- Diabetes mellitus
- Strict fasting
- Ongoing desensitisation therapy
- Heart problems
- History of psoriasis
- Thyrotoxicosis
- Peripheral circulatory disease
- Allergic
- General anaesthesia
- Tumour of the adrenal gland
- Pregnant
- Breast feeding

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

The following combination should be used with caution:

- Medicines with blood pressure lowering effects
- Medicines for treatment of heart disease
- Topical B-blocker (eg eye drops for glaucoma treatment)
- Insulin/oral antidiabetic agent
- anaesthetic agent
- NSAIDS

How to take Vasoten F.C. Tablets 5mg

How much to take

The usual initial dose is 5 mg bisoprolol (1 tablet of Vasoten 5 mg) once daily. If necessary, the dose may be increased to 10 mg bisoprolol (2 tablets of Vasoten 5 mg) once daily.

Treatment of hypertension or angina pectoris

The maximum recommended dose is 20 mg bisoprolol once daily.

Treatment of stable chronic heart failure

The treatment of stable chronic heart failure with bisoprolol is initiated according to the titration scheme, individual adaptation may be necessary depending on how well an individual tolerates each dose, i.e. the dose is to be increased only, if the previous dose is well tolerated.

Treatment is initiated with 1.25mg bisoprolol, the patient should be observed over a period of approximately 4 hours (especially as regards blood pressure, heart rate, conduction disturbances, and signs of worsening of heart failure).

Vasoten 5 mg is not suitable for initial treatment of stable chronic heart failure. Lower strengths are available for this purpose.

During the titration phase or thereafter, transient worsening of heart failure, fluid retention, hypotension or bradycardia may occur.

In this case it is recommended first to reduce the dose of bisoprolol. Bisoprolol should be discontinued only if clearly necessary, but its reintroduction and/or up titration should always be considered when the patient becomes stable again.

The maximum recommended dose is 10 mg bisoprolol once daily. Patients should be titrated to and maintained at this dose unless prevented by adverse effects.

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In all cases the dose regimen is adjusted individually by your doctor, in particular according to the pulse rate and therapeutic success.

Dosage is based on your medical condition and response to treatment. Use this medication regularly to get the most benefit from it.

When to take it

Take this medication by mouth with or without food, usually once a day or as directed by your doctor.

To help you remember, take it at the same time each day.

How long to take it

For the treatment of high blood pressure, it may take several weeks before you get the full benefit of this drug. It is important to continue taking this medication even if you feel well.

Duration of treatment for all indications

Treatment with Vasoten 5 mg is generally a long-term therapy. The treatment may be interrupted if necessary and reintroduced as appropriate.

Do not stop treatment abruptly or change the recommended dose without talking to your doctor first since this might lead to a transitory worsening of heart condition. Especially in patients with ischaemic heart disease, treatment must not be discontinued suddenly. If discontinuation is necessary, the dose is gradually decreased.

If you forget to take it

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to replace the missed one.

If you take too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking Vasoten F.C. Tablets 5mg

Things you must do

Tell your doctor immediately if you become pregnant.

Tell all doctors, dentists, pharmacists and diabetes educators who are involved with your treatment that you are taking this medicine.

Most people with high blood pressure do not feel sick. Tell your doctor if your condition does not improve or if it worsens (for example, your blood pressure readings remain high or increase).

Tell your doctor before you are undergoing general anaesthesia/surgery.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours. Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking your medicine, or change the dosage, without checking with your doctor.

Things to be careful of

Pregnancy and lactation:

Beta-blockers reduce placental perfusion, which may result in immature neonates or premature deliveries.

Many drugs are excreted in human milk; therefore breast-feeding is not recommended

during administration of bisoprolol.

Side effects

Skin and subcutaneous tissue disorders: itching, flush, rash, worsen psoriasis, alopecia

Heart problems: worsening of heart failure, chest pain, feeling of coldness or numbness in the extremities, low blood pressure

Nervous system disorders: dizziness, headache

Eye disorders: reduce tear flow, conjunctivitis

Ear disorder: hearing impairment

Gastrointestinal disorders: nausea, vomiting, diarrhoea, constipation

Musculoskeletal and connective tissue disorders: muscular weakness and cramps

General disorders: asthenia, fatigue

If you notice other side effects that you think are caused by this medicine, tell your doctor.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Vasoten F.C. Tablets 5mg

Storage

Store below 30°C and keep medicine out of reach of children. Vasoten tablets should be stored in the original container and should not be removed from their foil pack until required for administration.

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Disposal

Ask your pharmacist, doctor, or health caregiver about the best way to dispose of any leftover medicine after you have finished your treatment. You will also need to throw away old medicine after the expiration date has passed.

Keep all medicine away from children and never share your medicine with anyone.

Product Description

What it looks like?

Yellow to light-yellow, heart-shaped, biconvex film coated tablets, and vertically scored in half on both sides.

Ingredients

Active ingredient

Bisoprolol Fumarate

Inactive ingredients

Corn Starch, Deionized water, Microcrystalline cellulose (Avicel PH 101), Titanium Dioxide, Colloidal silicon dioxide, Polysorbate 80, Iron Oxide Yellow, Methylene Chloride, Polyethylene glycol 6000, Isopropyl Alcohol, Hydroxypropyl Methylcellulose, Dibasic Calcium Phosphate Powder Anhydrous (Fujicalin), Magnesium Stearate.

MAL11010010A

Manufacturer

Synmosa Biopharma Corporation,
Synmosa Plant, Taiwan
No.6, Kuang Yeh 1st Road, Hsin-Chu Ind. Park, Hsin Chu Hsien, Taiwan, R.O.C.

Product Registration Holder

Apex Pharmacy Marketing Sdn Bhd
No. 2, Jalan SS13/5, 47500 Subang Jaya, Selangor Darul Ehsan, Malaysia.

Date of Revision

12 October 2013