Bisocor® Plus

Bisoprolol Fumarate / Hydrochlorothiazide

Forms and presentation

Bisocor®5 Plus: Film coated tablets: Box of 30.

Bisocor®10 Plus: Film coated tablets: Box of 30.

Composition

Bisocor®5 Plus: Each film coated tablet contains Bisoprolol Fumarate 5mg, Hydrochlorothiazide 12.5mg.

Excipients: lactose, microcrystalline cellulose, dicalcium phosphate, crospovidone, colloidal silicon dioxide, magnesium stearate, polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, yellow iron oxide, FD&C yellow.

Bisocor®10 Plus: Each film coated tablet contains Bisoprolol Fumarate 10mg, Hydrochlorothiazide 25mg.

Excipients: lactose, microcrystalline cellulose, dicalcium phosphate, crospovidone, colloidal silicon dioxide, magnesium stearate, hypromellose, polyethylene glycol, talc, titanium dioxide, black iron oxide, red iron oxide.

Why should you take Bisocor®Plus?

Therapeutic class : Beta blocking agents.

ATC code : C07BB07.

Bisocor®Plus is prescribed to control high blood pressure. It is a combination of bisoprolol fumarate, a beta-blocker, with hydrochlorothiazide, a thiazide diuretic. Beta-blockers work by decreasing the force and rate of heart contractions, consequently leading to a reduction in the blood pressure. Diuretics help the body produce and eliminate more urine, which contributes also to lower blood pressure.

What should you know about Bisocor®Plus?

Bisocor®Plus helps control high blood pressure. Like other hypotensives, Bisocor®Plus is not a cure for essential hypertension. Stopping Bisocor®Plus suddenly may lead to cardiac problems, thus you should always stick to your physician's instructions and never stop the medication even if you are feeling well. This is especially important if you have coronary artery disease.

What is the recommended dosage of Bisocor®Plus?

ADULTS

The usual starting dose is 5mg of bisoprolol with 12.5mg of hydrochlorothiazide. Dosage may be increased to 10mg of bisoprolol with 25mg of hydrochlorothiazide in case blood pressure is not adequately controlled.

The usual starting dose may be very lower in asthmatics or in patients suffering from bronchial problems, kidney or liver diseases.

CHILDREN

Bisoprolol fumarate in combination with hydrochlorothiazide have not been adequately studied in children.

How is Bisocor®Plus taken?

Take Bisocor®Plus exactly as prescribed by your physician without skipping any doses, even when your symptoms have disappeared.

What to do if you miss a dose?

Take the forgotten dose as soon as you remember. If it is almost time for your next dose, skip the dose you missed and go back to your regular schedule. Do not take two doses at the same time.

What to do in case of over dosage?

Any medication taken in excess may lead to serious consequences. If you suspect an overdose of Bisocor®Plus, seek medical attention immediately.

Symptoms of Bisocor®Plus overdose may include:

Congestive heart failure (marked by fatigue, shortness of breath, sudden weight gain, lower limbs edema including legs, feet, and ankles), difficulty in breathing, decreased or increased heart rate, hypotension, decreased blood sugar, decreased or increased urination, fluid or electrolyte loss, abnormal skin sensations, cramps in the calf muscle, confusion, dizziness, drowsiness, impaired consciousness, weakness, nausea, shock, thirst, vomiting.

In case of large overdoses, that may interfere with breathing or cause delirium, convulsions, or coma.

Are there food or drug interactions with Bisocor®Plus?

Bisocor® Plus can be taken concomitantly with most medications. However it is important to consult your physician before combining Bisocor®Plus with any of the following:

Blood pressure drugs including the calcium-blockers (such as diltiazem, disopyramide, and verapamil), clonidine, disopyramide and similar drugs used to treat irregular heartbeat, , epinephrine, norepinephrine, rifampin, guanethidine, reserpine, oral anti-diabetics, insulin, nonsteroidal anti-inflammatory drugs (such as acetylsalicylic acid, ibuprofen, acetaminophen), painkillers (such as codeine or morphine), steroids (such as prednisone), muscle relaxants (such as tubocurarine), lithium, barbiturate sedatives (such as secobarbital and pentobarbital), cholesterol-lowering drugs (such as colestipol and cholestyramine), and alcohol.

What are the side effects of Bisocor®Plus?

Common side effects are: dizziness and fatigue.

Frequency 'not known': Skin and lip cancer (Non-melanoma skin cancer).

Inform your physician about any other unusual symptoms.

Precautions about Bisocor® Plus

if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Bisocor® Plus.

Treatment with Bisocor® Plus must not be stopped abruptly unless recommended by your physician. If you have to interrupt your treatment with Bisocor®Plus, your physician will gradually lower your dose over a period of 2 weeks.

Bisocor®Plus must be used with caution in patients with asthma or bronchial problems, kidney or liver diseases, coronary artery disease, and peripheral vascular disease.

Consult your physician if you have a history of congestive heart failure, and suffered from any breathing problems, or slow heart beat while on therapy with Bisocor®Plus.

Bisocor®Plus may mask the symptoms of low blood sugar, or affect blood sugar levels, and may mask the symptoms of overactive thyroid.

Bisocor®Plus may alter the response to epinephrine in patients with history of severe allergic reactions that require treatment with epinephrine.

Bisocor®Plus may decrease alertness or make some people drowsy, so do not drive or participate in hazardous activities until you know how your body responds to the medication.

You should inform your physician or dentist that you are taking Bisocor®Plus before any dental operation or other surgery or in cases of medical emergency.

In case of systemic lupus erythematosus, Bisocor®Plus may aggravate the symptoms.

In few patients, bisoprolol fumarate in combination with hydrochlorothiazide caused an increase in calcium and phosphate blood levels due to interfering with parathyroid function. Gout has also appeared in rare cases.

There is a slight possibility that Bisocor®Plus could cause a decrease in blood levels of some electrolytes such as potassium and magnesium. Inform your physician if you develop any of the following: excessive thirst, dry mouth, gastrointestinal problems such as nausea and vomiting, drowsiness, restlessness, weakness or muscle fatigue, muscle pains or cramps, hypotension, tachycardia, or an unusual decrease in urination.

What are the cases in which you should not take Bisocor®Plus?

Inform your physician in case you have bronchial asthma, low blood supply to the circulatory system or other cardiac problems such as congestive heart failure, irregular or slow heartbeat, or trouble urinating.

Do not use Bisocor®Plus if you are allergic to the drug or to some antibiotics called sulfonamides such as sulfamethoxazole.

What should you do if you are pregnant or breastfeeding?

Bisoprolol fumarate in combination with hydrochlorothiazide has not been adequately studied during pregnancy, thus inform your physician if you are pregnant or planning to become pregnant while on therapy with Bisocor®Plus.

It is not known if Bisocor®Plus is secreted in breast milk, thus your physician will inform you what to do if you are breastfeeding while on therapy with Bisocor®Plus. If this drug is essential to your health, your physician may advise you to discontinue breastfeeding until your treatment with Bisocor®Plus is finished.

How to store Bisocor®Plus?

Store below 30ºC.

Keep in original pack in intact conditions.

Date of revision: November 2018

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

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