PACKAGE LEAFLET: Information for the patient

PROCOR

Film-coated tablets – 5 mg, 10 mg

(Bisoprolol fumarate)

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 question, ask your doctor or pharmacist.
- This medication 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 PROCOR IS AND WHAT IT IS USED FOR

Procor contains the active substance bisoprolol fumarate which is a cardioselective beta-blocker. Bisoprolol is an intrinsic sympathomimetic and has membrane-stabilising properties. The antihypertensive effect of beta-blockers occurs as a result of the direct action on the heart by reducing cardiac output, contraction and cardiac frequency, by reducing renin production from juxtaglomerular apparatus, and by causing inhibitory effects in the central nervous system (CNS).

Procor is given as the fumarate in the management of hypertension and angina pectoris. It is also

used as an adjunct to standard therapy in patients with stable chronic heart failure.

2. BEFORE YOU TAKE PROCOR

Do not take Procor if you suffer from:

- hypersensitivity to bisoprolol fumarate or to any of the excipients of Procor;
- uncontrolled heart failure;
- Prinzmetal's angina;
- marked bradycardia;
- sick sinus syndrome;
- AV block of second or third degree;
- cardiogenic shock;
- metabolic acidosis;
- severe peripheral arterial disease;
- phaeochromocytoma;
- sino-atrial block;
- acute or decompensated heart failure requiring intravenous inotropes;
- symptomatic hypotension;
- severe bronchial asthma or chronic obstructive pulmonary disease.

Take special care with Procor

Talk to your doctor or pharmacist before taking Procor.

Beta-blockers should not be given to patients with bronchospasm or asthma or to those with a history of obstructive airways disease.

Beta-blockers may mask the symptoms of hyperthyroidism and of hypoglycaemia. They may unmask myasthenia gravis. Psoriasis may be aggravated.

Use of beta-blockers in pregnancy shortly before delivery has occasionally resulted in bradycardia and other adverse effects such as hypoglycaemia and hypotension in the neonate.

Many beta blockers are distributed into breast milk.

Abrupt withdrawal of beta-blockers has sometimes resulted in angina, myocardial infarction, ventricular arrhythmias, and death. Patients on long-term treatment with a beta-blocker should have their medication stopped gradually over a period of 1 to 2 weeks.

Taking other medicines

Drugs that can interact with bisoprolol are: alpha-blockers (prazosin), anti-arrhythmics (amiodarone, disopyramide, dronedarone, flecainide, lidocaine, propafenone), antibacterials (rifampicin), antidepressants, antimalarials, antipsychotics, calcium-channel blockers (nifedipine, diltiazem, verapamil), clonidine, diuretics, aminophylline, theophylline, antiepileptics (phenobarbital, primidone), ergometrine, ergotamine, sympathomimetics (dobutamine, adrenaline, noradrenaline) and moxisylyte.

Alpha-blockers: enhanced hypotensive effect when beta-blockers are given with alpha-blockers, also increased risk of first-dose hypotension with postsynaptic alpha-blockers such as prazosin.
Anti-arrhythmics: increased myocardial depression when beta-blockers given with anti-arrhythmics. They increase the risk of myocardial depression and bradycardia when beta-blockers given with flecainide.
Antibacterials: metabolism of bisoprolol accelerated by rifampicin.
Antidepressants: enhanced hypotensive effect when beta-blockers given with MAOIs.
Antimalarials: increased risk of bradycardia when beta-blockers given with mefloquine.
Antipsychotics: enhanced hypotensive effect when beta-blockers given with phenothiazines.
Calcium-channel blockers: enhanced hypotensive effect when beta-blockers given with calcium-channel blockers; possible severe hypotension and heart failure when beta-blockers given with nifedipine, increased risk of AV block and bradycardia when beta-blockers given with diltiazem; asystole, severe hypotension and heart failure when beta-blockers given with verapamil.
Clonidine: increased risk of beta-blockers withdrawal hypertension.
Diuretics: enhanced hypotensive effect when beta-blockers given with diuretics.
Aminophylline and theophylline: selective beta-blockers may increase the risk of bronchospasm when given with any of these medicines.
Antiepileptics: phenobarbital and primidone may decrease the exposure to selective beta-blockers.
Ergometrine and ergotamine: selective beta-blockers may increase the risk of peripheral vasoconstriction when given with any of these drugs.
Sympathomimetics: selective beta-blockers may increase the risk of hypertension and bradycardia when given with dobutamine, adrenaline or noradrenaline.

Moxisylyte: possible severe postural hypotension when beta-blockers are given with moxisylyte.

Pregnancy and breastfeeding

Pregnancy

If you are pregnant, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medication.

Beta-blockers may cause intra-uterine growth restriction, neonatal hypoglycaemia, and bradycardia; the risk is greater in severe hypertension. Bisoprolol should not be used during pregnancy.

Breastfeeding

If you are breastfeeding, ask your doctor or pharmacist for advice before taking this medication. Data on bisoprolol usage are controversial, therefore breast-feeding is not recommended during administration of bisoprolol.

Driving and using machines

No studies have been performed on the ability to drive and use machines. Anyway, you should not drive or operate machinery after receiving the drug, as there may be residual dizziness and vertigo.

Important information about some of the excipients of Procor

This medicinal product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE PROCOR

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:

In hypertension or angina pectoris the usual dose of bisoprolol fumarate is 5 to 10 mg orally as a single daily dose; the maximum recommended dose is 20 mg daily. A reduction in dose may be necessary in patients with hepatic or renal impairment.

In stable chronic heart failure the initial oral dose of bisoprolol fumarate is 1.25 mg once daily. If tolerated, the dose should be doubled after 1 week, and then increased gradually at 1- to 4-week intervals to the maximum dose tolerated; this should not exceed 10 mg once daily.

Administration in hepatic or renal impairment.
It is recommended a maximum dose of 10 mg daily for both angina pectoris and hypertension in patients with severe hepatic impairment or with a creatinine clearance of less than 20 mL/minute. Bisoprolol is not dialysable.

If you take more Procor than you should
Do not take more Procor than the amount that your doctor recommends.
Beta-blockers overdosages are uneventful, but some patients develop severe and occasionally fatal cardiovascular depression. Effects can include bradycardia, cardiac conduction block, hypotension, heart failure, and cardiogenic shock. Convulsions, coma, respiratory depression, and bronchoconstriction can also occur, although infrequently.

Treatment
Atropine, glucagon, and sympathomimetics are the mainstay of treatment for severe beta - blocker overdosage.

If you forget to take Procor
Do not take a double dose to make up for a forgotten dose.
If you forget to take Procor, take your dose as soon as you remember unless it is time to take the next dose. Use doses at the right time.

If you stop taking Procor
Treatment with Procor must not be stopped abruptly. If you suddenly stop the use of Procor, your condition may get worse or your blood pressure may start to rise again. If you have any further questions on the use of this medicine, ask your doctor, or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, bisoprolol can cause side effects, although not everybody gets them.
Beta-blockers are generally well tolerated and most adverse effects are mild and transient.
Possible side effects are: bradycardia, heart failure, hypotension, peripheral vasoconstriction, conduction disorders, bronchospasm, gastro-intestinal disturbances, dyspnoea, headache, fatigue, sleep disturbances, paraesthesia, dizziness, vertigo, psychoses, sexual dysfunction, purpura, thrombocytopenia, visual disturbances, exacerbation of psoriasis, alopecia, rarely hypertriglyceridaemia, syncope and hearing impairment, rashes and dry eyes (reversible on withdrawal); also less commonly depression, muscle weakness, and cramps; very rarely conjunctivitis, flushing, hepatitis, hypersensitivity, pruritus.
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 PROCOR

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the package.
Store in a temperature below 25°C!
Keep Procor away from the sun and humidity!
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. OTHER INFORMATION

What Procor film-coated tablets contain

The **active substance** is bisoprolol fumarate.
Each film-coated tablet 5 mg contains 5 mg bisoprolol fumarate.
Each film-coated tablet 10 mg contains 10 mg bisoprolol fumarate.

The **excipients** for Procor 5 mg are:
tablet core: lactose monohydrate, microcrystalline cellulose, crospovidone, magnesium stearate,
film-coating: polyvinyl alcohol, titanium dioxide, macrogol, talc.

The **excipients** for Procor 10 mg are:
tablet core: lactose monohydrate, microcrystalline cellulose, crospovidone, magnesium stearate,
film-coating: polyvinyl alcohol, titanium dioxide, macrogol, talc, yellow iron oxide, red iron oxide, black iron oxide.

Contents of the pack

Procor 5 mg: carton box with 30 film-coated tablets.
Procor 10 mg: carton box with 30 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,
St. "Skënder Vila",
Tirana, Albania.
Tel.: +355 4 23 89 602

This leaflet was last revised in October 2023.