

Egypro

Bisoprolol Fumarate

Tablets



1-Company Name:

Egyptian Group For Pharmaceutical Industries.

2-Trade Name: Egypro 5mg, Egypro 10mg.

3-Generic Name:

Each tablet of Egypro 5 mg contains:

5 mg bisoprolol fumarate.

Each tablet of Egypro 10 mg contains:

10 mg bisoprolol fumarate.

4-Composition:

Each tablet of Egypro 5 mg contains:

5 mg bisoprolol fumarate.

Each tablet of Egypro 10 mg contains:

10 mg bisoprolol fumarate.

5-Pharmaceutical form: Tablets.

6-Pharmacological Actions:

Egypro is a cardioselective beta blocker.

- Bisoprolol block the beta- adrenoreceptors in the heart.

- Bisoprolol has an intrinsically longer duration of action and need to be given only once daily.

- Bisoprolol reduce cardiac output, alter baroreceptor reflex sensitivity.

- By reducing cardiac work beta-blockers improve exercise tolerance and relive symptoms in patients with angina.

- Beta-blockers act as anti-arrhythmic drugs principally by attenuating the effects of the sympathetic system on automaticity and conductivity within the heart.

- Beta-blockers may produce benefit in the heart failure by blocking sympathetic activity.

- Bisoprolol has a lesser effect on airways resistance.

7-Pharmacokinetics

Bisoprolol is almost completely absorbed from the gastrointestinal tract and undergoes only minimal first-pass metabolism resulting in an oral bioavailability of about 90%. Peak plasma concentrations are reached 2 to 4 hours after oral administration. Bisoprolol is about 30% bound to plasma proteins. It has a plasma elimination half-life of 10 to 12 hours. Bisoprolol is moderately lipid-soluble. It is metabolised in the liver and excreted in urine, approximately 50% as unchanged drug and 50% as metabolites.

8-Indications:

Egypro is indicated in the following conditions:

- Hypertension.
- Coronary heart disease (Angina Pectoris).
- Stable chronic heart failure.

9-Dosage:

The treatment should be initiated with low dose and then increased gradually. In all cases the dosage should be adjusted individually.

Hypertension & Angina Pectoris:

Unless otherwise prescribed, The recommended dose is Egypro 5 mg once daily.

If the effect is inadequate, The dose can be increased to Egypro 10mg once daily. A further dosage increase is only in exceptional cases.

Stable chronic heart failure: Dosage should be started with 1.25 mg daily then increased by 1.25 mg on weekly basis till reaches 5 mg daily. The 5 mg daily is given for 4 weeks if found tolerated but inadequate to 7.5 mg once daily for 4 weeks then to 10 mg once daily as maintenance dose.

10-Mode of administration:

Egypro should be swallowed with some liquid.

Egypro can be taken with or without food.

It is preferred to take Egypro in the morning.

11-Contra-Indications:

- Acute heart failure.
- AV block grades II and III.
- Sino-atrial block.
- Marked bradycardia.
- Decompensated heart failure.
- Cardiogenic shock.
- Hypotension.
- Sick sinus syndrome.
- Metabolic acidosis
- Severe peripheral arterial disease.
- Pheochromocytoma.
- Prinzmetal s angina.
- Asthma

12-Adverse effects:

Particularly at the start of the treatment mild headache, dizziness, tiredness may occur. These symptoms are usually mild in nature and mainly recede within 1-2 weeks after the beginning of the treatment.

GIT disturbances (diarrhea, constipation, nausea, abdominal pain), muscle cramp and muscle weakness. Occasionally a marked decrease in blood pressure, slow pulse rate, tingling, heart failure conduction disorders, bronchospasm, peripheral vasoconstriction

In rare cases rashes, dry eyes sexual dysfunction and exacerbation of psoriasis.

13-Drug interactions:

Reserpine, α - methyl dopa, clonidine, guanfacine,

nifedipine, NSAIDS,

Mono amine oxidase inhibitors & rifampin.

Prior to any operation the anesthetist should be informed.

14-Pregnancy & Lactation:

In general beta blockers reduce placental blood.

Breast feeding is not recommended during Bisoprolol therapy.

15- Precautions & Warning:

Egypro should not be discontinued without the doctor's directions.

The treatment with Egypro must not be discontinued abruptly but must be discontinued on a gradual basis. Be caution with first degree AV block, portal hypertension, diabetes, history of obstructive airways disease, myasthenia gravis, history of hypersensitivity.

16-Package & Storage:

Egypro 5mg:

Carton box contains 10 tablets in one strip(PVC/AL) and inner leaflet.

Carton box contains 20 tablets in two strips(PVC/AL) and inner leaflet.

Carton box contains 30 tablets in three strips(PVC/AL) and inner leaflet.

Egypro 10mg:

Carton box contains 10 tablets in one strip(PVC/AL) and inner leaflet.

Carton box contains 20 tablets in two strips(PVC/AL) and inner leaflet.

Storage not exceeding 30°C in a dry place.

Manufactured by:

Egyptian group for pharmaceutical industries- Egypt

