Only for the use of Medical Professionals

Probis®

Bisoprolol Fumarate

Description

Probis® is a preparation of Bisoprolol fumarate which is β1-selective (cardioselective) adrenoceptor blocking agent without significant membrane stabilizing activity or intrinsic sympathomimetic activity in its therapeutic dosage range. It blocks the action of the sympathetic nervous system on the heart by blocking the heart's β_1 -adrenergic receptors. It reduces the heart rate & force of contraction of the heart, thus lowers blood pressure.

Indications

Probis® is indicated for the management of essential hypertension, angina pectoris & heart failure. It may be used or alone in combination with other anti hypertensive agents.

Dosage and administration

For Essential Hypertension and Angina pectoris: The usual starting dose is 5 mg once daily. In some patients, 2.5 mg may be an appropriate starting dose. If the antihypertensive effect of 5 mg is inadequate, the dose may be increased to 10 mg and then, if necessary, to 20 mg once daily.

For Heart failure: Initially 1.25 mg once daily (in the morning) for 1 week then, if well tolerated, increased to 2.5 mg once daily for 1 week, then 3.75 mg once daily for 1 week, then 5 mg once daily for 4 weeks, then 7.5 mg once daily for 4 weeks, then 10 mg once daily; max. 10 mg daily.

Geriatric Patients: It is not necessary to adjust the dose in the elderly, unless there is also significant renal or hepatic dysfunction.

Pediatric Patients: There is no pediatric experience with this.

Use in pregnancy & lactation

Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. This should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known whether this drug is excreted in human milk. Therefore, caution should be exercised when it is administered to nursing mother.

Side effects

The most common side effects includes Diarrhea; dizziness; drowsiness; fatigue; headache; lightheadedness; nausea; sleeplessness; unusual tiredness; weakness. It can also shows severe allergic reactions (rash; hives; itching, difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); chest pain; difficulty breathing; lightheadedness or dizziness when rising from a lying or sitting position; very slow heartbeat in rare cases.

Precautions

Impaired renal or hepatic function: Use caution in adjusting the dose of Bisoprolol in patients with renal or hepatic impairment. Risk of anaphylactic reaction: While taking β-blockers, patients with a history of severe anaphylactic reaction to a variety of allergens may be more reactive to repeated challenge, accidental, diagnostic or therapeutic. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reaction.

Contraindications

Bisoprolol is contraindicated in patients with cardiogenic shock, overt cardiac failure, second or third degree AV block, and marked sinus bradycardia. It is also contra indicated in patients with known hypersensitivity of any of the components.

Drug interaction

Bisoprolol should not be combined with other β-blocking agents. Patients receiving catecholamine-depleting drugs should be closely monitored, because the added beta-adrenergic blocking action of Bisoprolol may produce excessive reduction of sympathetic activity.

In patients receiving concurrent therapy with clonidine, if therapy is to be discontinued, it is suggested that Bisoprolol be discontinued for several days before the withdrawal of clonidine. Bisoprolol should be used with care when myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists or antiarrhythmic agents are used concurrently.

Concomitant use with digitalis glycosides can increase the risk of bradycardia.Concurrent use of rifampin increases the metabolic clearance of Bisoprolol, resulting in a shortened elimination half-life of Bisoprolol. However, initial dose modification is generally not necessary.

Overdose

The most common signs expected with overdosage of a β-blocker are bradycardia, hypotension, congestive heart failure, bronchospasm, and hypoglycemia. In general, if overdose occurs, Bisoprolol therapy should be stopped and supportive and symptomatic treatment should be provided.

Pharmaceutical precautions

Store in a cool & dry place protected from light. Keep away from the reach of children.

Presentation

Probis® 2.5 tablet: Each coated tablet contains Bisoprolol Fumarate USP 2.5 mg.
Probis® 5 tablet: Each coated tablet contains Bisoprolol Fumarate USP 5 mg.

Package quantities

Probis® 2.5 tablet: Carton of 30 tablets in blister pack.
Probis® 5 tablet: Carton of 30 tablets in blister pack.

ACI Limited