Conbis™

Bisoprolol Fumarate

Composition:

Conbis™ 2.5 Tablet: Each film coated tablet contains Bisoprolol Fumarate USP 2.5 mg.

Conbis™ 5 Tablet: Each film coated tablet contains Bisoprolol Fumarate USP 5 mg.

Description:

Conbis™ (Bisoprolol Fumarate) is a beta1-selective adrenoceptor blocking agent. Conbis™ mainly blocks betal-receptors in the heart, this causes the heart to beat more slowly and with less force, which means the heart uses less energy and so requires less oxygen. The pain of angina is caused by not enough oxygen reaching to the heart muscle when its workload is increased. **Conbis™** therefore prevents this pain by decreasing the oxygen demand of the heart, so that it always has a sufficient supply. Due to the heart beating more slowly and with less force, the pressure at which blood is pumped out of the heart to the rest of the body is reduced. This is just one of the ways in which **Conbis™** helps to reduce blood pressure. It only shows very low affinity to the beta2-receptor of the smooth muscle of bronchi & vessels as well as to the beta2- receptors concerned with metabolic regulation.

Indications:

Treatment of high blood pressure (Hypertension), Treatment of Coronary heart disease (Angina Pectoris) and Treatment of stable chronic moderate to severe heart failure with reduced systolic ventricular function (ejection fraction 35% based on echocar- diography) in addition to ACE inhibitors, diuretics & optionally cardiac alvoosides.

Dosage & Administration:

Treatment of hypertension & angina pectoris:

Conbis™ tablet is taken in the morning with or without food. The usual initial dose is 5 mg once daily. If necessary, the dose may be increased to 10 mg once daily. The maximum recommended dose is 20 mg once daily.

Treatment of stable chronic heart failure:

5 mg of Bisoprolol Fumarate is not suitable for the initial treatment of stable chronic heart failure. The dosage quideline is as follows-

 1^{st} week : 1.25 mg once daily

 $\begin{array}{lll} 2^{nd} \text{ week} & : 2.5 \text{ mg once daily} \\ 3^{rd} \text{ week} & : 3.75 \text{ mg once daily} \\ 4^{th}-7^{th} \text{ week} & : 5 \text{ mg once daily} \\ 8^{th}-11^{th} \text{ week} & : 7.5 \text{ mg once daily} \end{array}$

12th week & beyond: 10 mg once daily as maintenance treatment. The maximum recommended dose is 10 mg once daily.

OR AS DIRECTED BY THE PHYSICIAN.

Side Effects:

Depression, nightmares, hallucinations, dizziness, headache, sleep disturbance, reduced tear flow & conjunctivitis occurs in very rare case, hearing disturbances, bradycardia, cold extremities, bronchospasm in patients with bronchial asthma, allergic rhinitis, gastrointestinal complaints such as nausea, vomiting, diarrhea, constipation, hypersensitivity reactions such as itching, skin rash, tiredness, increased triglyceride level may occur.

Precautions:

Bisoprolol Fumarate should be prescribed with caution in patients with diabetes mellitus, strict fasting, first-degree AV block, Prinzmetal's angina, psoriasis or family history of psoriasis, history of obstructive disease, myasthenia gravis etc.

Pregnancy: During pregnancy, Bisoprolol Fumarate should only recommended following careful assessment. This drug can be given only on third trimester.

Lactation: Though amount of beta-blockers present in breast milk is too small to affect infant, caution should be exercised during lactation.

Drug Interactions:

Bisoprolol Fumarate should not be combined with other betablocking agents. Patients receiving catecholamine-depleting drugs, such as reserpine or quanethidine, should be closely monitored, because the added beta-adrenergic blocking action of Bisoprolol Fumarate 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 Furnarate should be discontinued for several days before the withdrawal of clonidine. Bisoprolol Fumarate should be used with care when myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists, or antiarrhythmic agents, such as disopyramide, are used concurrently. Concurrent use of rifampin increases the metabolic clearance of Bisoprolol Fumarate, resulting in a shortened elimination half-life of Bisoprolol Fumarate. However, initial dose modification is generally not necessary. There was no effect of Bisoprolol Fumarate on prothrombin time in patients on stable doses of warfarin, Risk of Anaphylactic Reaction: While taking beta-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 reactions.

Contraindications:

Bisoprolol Fumarate is contraindicated in patients with severe bronchial asthma or severe obstructive pulmonary disease, uncontrolled heart failure, sinoatrial block, bradycardia, hypotension, sick sinus syndrome, second-or third-degree AV block, metabolic acidosis, severe peripheral arterial disease, hypersensitivity to Bisoprolol Fumarate or any other components of this preparation.

Storage Condition:

Store in a cool & dry place, protect from light. Keep out of the reach of children

Presentation:

Conbis™ 2.5 Tablet: Each box contains 3x10's tablets in blister pack.

 ${f Conbis}^{{\mbox{\tiny TM}}}$ 5 Tablet: Each box contains 3x10's tablets in blister pack.

Manufactured by: