

Bisoprolol Fumarate USP + Hydrochlorothiazide BP

COMPOSITION:

Ancor Plus-2.5 Tablet: Each film-coated tablet contains Bisoprolol Fumarate USP 2.5 mg and Hydrochlorothiazide BP 6.25 mg.

Ancor Plus-5 Tablet: Each film-coated tablet contains Bisoprolol Fumarate USP 5 mg and Hydrochlorothiazide BP 6.25 mg.

PHARMACOLOGY:

Bisoprolol and HCTZ have been used individually and in combination for the treatment of hypertension. The antihypertensive effects of these agents are additive; HCTZ 6.25 mg significantly increases the antihypertensive effect of Bisoprolol. The incidence of hypokalemia with the Bisoprolol and HCTZ 6.25 mg combination is significantly lower than with HCTZ 25 mg.

Bisoprolol is a beta1-selective adrenoceptor-blocking agent without significant membrane stabilizing or intrinsic sympathomimetic activities in its therapeutic dose range.

Hydrochlorothiazide is a benzothiadiazine diuretic. Thiazides affect renal tubular mechanisms of electrolyte reabsorption and increase excretion of sodium and chloride in approximately equivalent amounts.

INDICATION:

Ancor Plus is indicated for the management of hypertension.

DOSAGE & ADMINISTRATION:

The initial dose is 2.5/6.25 mg once daily. Subsequent titration (14 day intervals) may be carried out with Ancor Plus tablets up to the maximum recommended dose 20/12.5 mg once daily, as appropriate.

Therapy Guided by Clinical Effect

A patient whose blood pressure is not adequately controlled with 2.5-20 mg Bisoprolol daily may instead be given Ancor Plus. Patients whose blood pressures are adequately controlled with 50 mg of Hydrochlorothiazide daily, but who experience significant potassium loss with this regimen, may achieve similar blood pressure control without electrolyte disturbance if they are switched to Ancor Plus.

Replacement Therapy

The combination may be substituted for the titrated individual components.

Cessation of Therapy

If withdrawal of Ancor Plus therapy is planned, it should be achieved gradually over a period of about 2 weeks. Patients should be carefully observed

CONTRAINDICATIONS:

It is contraindicated in patients in cardiogenic shock, overt cardiac failure, second or third degree AV block, marked sinus bradycardia, anuria and hypersensitivity to either component of this product or to other sulfonamide-derived drugs.

PRECAUTIONS:

Hyperuricemia or acute gout may be precipitated in certain patients receiving thiazide diuretics. Warning signs or symptoms of fluid and electrolyte imbalance include dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia and gastrointestinal disturbances such as nausea and vomiting. Hypokalemia may develop.

SIDE EFFECTS:

Generally well-tolerated. Most side effects are mild and transient. The common side effects fatigue, dizziness, headache, bradycardia, peripheral ischemia, palpitations, rhythm disturbances, claudication, orthostatic hypotension, diarrhoea, constipation, nausea, dyspepsia, rhinitis, pharyngitis etc.

USE IN SPECIAL GROUP:

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

Use in Nursing Mothers: Bisoprolol alone or in combination with Hydrochlorothiazide has not been studied in nursing mothers.

DRUG INTERACTIONS:

This combination drug may potentiate the action of other antihypertensive agents when used concomitantly. This combination drug should not be combined with other beta-blocking agents. Patients receiving catecholamine-depleting drugs, such as reserpine or guanethidine, should be closely monitored because the added beta-adrenergic blocking action of Bisoprolol may produce excessive reduction of sympathetic activity. This combination should be used with caution when myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists verapamil and benzothiazepine diltiazem classes or anti-arrhythmic agents, such as disopyramide, are used concurrently. Both digitalis glycosides and beta-blockers slow atrioventricular conduction and decrease heart

STORAGE:

- Store below 30°C, keep in dry place & protect from light.
- Keep out of the reach of children.

PACKING:

Ancor Plus-2.5 Tablet: Each box contains 30 tablets in alu-alu blister pack. **Ancor Plus-5** Tablet: Each box contains 30 tablets in alu-alu blister pack.

