Low-dose composition minimizes overall incidence of side effects

- ZIAC avoids beta-blocker-associated side effects
  - The two most common side effects—dizziness (3.2%) and fatigue (3.0%)—occurred at rates comparable to placebo
- ZIAC has a low incidence of cough (1.5%), peripheral edema (0.9%), and headache (0.4%)—which occurred at rates comparable to placebo

Up to 80% of patients controlled with equivalent efficacy regardless of age, race, or gender

ZIAC 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.

*Clinical trial response rates were: 2.5 mg—61%; 5 mg—73%; 10 mg—80%.
Please see Brief Summary of Prescribing Information on adjacent page.
Bisoprolol fumarate on prothrombin and transient.

Other agents given concomitantly, including that depress myocardial function, such as ether, cyclopropane, and trichloroethylene, are used.

Drug Interactions: ZIAC

post-sympathectomy patient.

bradycardia, anuria, and hypersensitivity to

Cardiac failure: Beta-blocking

spasm have been rare. Discontinuation rates for AEs were

Half-life

Data on file, Lederle Laboratories, River, NY, 1995 Lederle Laboratories

Summary

Bisoprolol fumarate/HS.25 mg is well tolerated in most patients. Most adverse effects (AEs) have

Anosmia may precipitate

to the followmg

emotional lability,

ventricular

without signs of
to other

The administration of a nonsteroidal anti-inflammatory


Two AE categories were

patients receiving insulin or oral hypoglycemic

Increase In

Cardiovascular:

other adverse experiences that have been reported with the individual components are listed below.

Body System/ Adverse Experience

Under License of E. MERCK

ZIAC (Bisoprolol Fumarate and Hydrochlorothiazide) Tablets

Precautions

ZIAC be discontinued

SB.

ADVERSE REACTIONS

ZIAC (Bisoprolol Fumarate and Hydrochlorothiazide) Tablets

References:


Brief Summary

Dosages

Body as a Whole

Central Nervous System

Myocardial ischemia: Reduced cardiac output (SB. 1 to 3.5 mm Hg) is associated with increases in serum trypsin inhibitors. Mean increases in serum trypsin inhibitors were observed in patients treated with bisoprolol fumarate and hydrochlorothiazide 6.25 mg. Total cholesterol was generally unaffected, but small decreases in HDL cholesterol were observed.

Other laboratory abnormalities that have been reported with the individual components are listed below.

Table of AE categories and frequencies

Assays of serum electrolytes should be performed, and patients should be observed for signs of fluid or electrolyte disturbances. Thiabendazole have been shown to increase the urinary excretion of magnesium, this may result in hypomagnesemia.

ZIAC: Should be used with caution in patients with impaired hepatic function or progressive liver disease.

Hydralazine may develop. Hydralazine and hydrazine can provoke ventricular arrhythmias or sensory of exaggerate the response of the heart to the toxic effects of digoxin.

Diabetes and obesity are common complications. The manifestations of hypoglycemia, particularly tachycardia. Patients subject to spontaneous hypoglycemia, or diabetic patients receiving insulin or oral hypoglycemic agents, should be considered.

Vasoconstriction

ZIAC:

Hypokalemia and hypomagnesemia can provoke ventricular

Bedside Laboratory

Drug-Related Adverse Experiences

Comparison of 4-week treatment periods at least 2% of bisoprolol fumarate HS.25 mg-treated patients (plus additional selected adverse experiences) are presented in the following table:

Other than adverse experiences that have been reported with the individual components are listed below.

Bisoprolol Fumarate: In clinical trials worldwide, a variety of other AEs have been listed above, have been observed in relatively few patients, and were not considered to be related to the drug. There were no special issues for ZIAC in these trials.

In the United States, 252 patients received bisoprolol fumarate (2.5, 5, or 10, or 40 mg) HS.25 mg and 144 patients received placebo in two controlled trials. In Study 1, bisoprolol fumarate 5/4 mg, 25 mg was administered for 12 weeks. All adverse experiences, whether drug-related or not, and drug-related adverse experiences in patients treated with 87/140-160 mg, etc. Concerning clozapine, 4-week treatment periods by at least 2% of bisoprolol fumarate HS.25 mg-treated patients (plus additional selected adverse experiences) are presented in the following table:

Other than adverse experiences that have been reported with the individual components are listed below.

ZIAC (Bisoprolol Fumarate and Hydrochlorothiazide) Tablets

FOR FULL PRESCRIBING INFORMATION, PLEASE CONSULT PACKAGE INSERT.

WARNING

Cardiac Failure: Beta-blockers should be avoided in patients with overt congestive failure.

Patients Without a History of Cardiac Failure: Continued depression of the myocardium with beta-blockers can precipitate cardiac failure in patients with latent cardiac disease. Patients with a history of cardiac failure should be considered.

Aplastic Anemia: Therapy: Abrupt cessation of beta-blockers should be avoided. In patients without overt coronary artery disease, it may be advisable to taper therapy with ZIAC over approximately 1 week with the patient under careful observation. If withdrawal symptoms occur, beta-blocker therapy should be reinstated, at least temporarily.

Peripheral Vascular Disease: Beta-blockers should be used with caution in patients with peripheral vascular disease.

Bronchospastic Disease: PATIENTS WITH BRONCHOSPASTIC PULMONARY DISEASE SHOULD, IN GENERAL, NOT RECEIVE BETA-BLOCKERS.

Azotemia, anuria, and hypersensitivity to thiazide derivatives.

Study "

Patients receiving bisoprolol fumarate 2.5, 5,

Bisoprolol fumarate (2.5, 5, 10 mg) and placebo-treated patients.

Bisoprolol fumarate (2.5, 5, 10, or 40 mg) HS.25 mg and 144 patients received placebo in two controlled trials. In Study 1, bisoprolol fumarate 5/4 mg, 25 mg was administered for 12 weeks. All adverse experiences, whether drug-related or not, and drug-related adverse experiences in patients treated with 87/140-160 mg, etc. Concerning clozapine, 4-week treatment periods by at least 2% of bisoprolol fumarate HS.25 mg-treated patients (plus additional selected adverse experiences) are presented in the following table:
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