For first-line therapy in mild-to-moderate hypertension

Discover the classic benefits of a beta-blocker and a diuretic...now at low doses for a side-effect profile comparable to placebo

ZIAC controls mild-to-moderate hypertension in up to 80% of patients

ZIAC controls blood pressure for a full 24 hours for true once-a-day dosing

ZIAC minimizes traditional beta-blocker- and HCTZ-associated metabolic effects (hypokalemia, hyperuricemia, hypercholesterolemia, hyperglycemia)

*The two most common side effects — dizziness and fatigue — occurred at rates comparable to placebo.

*Clinical trial response rates were: 2.5 mg—61%; 5 mg—73%; 10 mg—80%.

ZIAC is contraindicated in patients in cardiogenic shock, overt cardiac failure (see WARNINGS section of full Prescribing Information), second- or third-degree AV block, marked sinus bradycardia, anuria, and hypersensitivity to either component of this product or to other sulfonamide-derived drugs.

Please see Brief Summary of Prescribing Information on adjacent page.

First-line therapy option

ZIAC
(bisoprolol fumarate-hydrochlorothiazide)
2.5, 5, & 10 mg Tablets with 6.25 mg HCTZ
ZIAC™ (Bisoprolol Fumarate and Hydrochlorothiazide) Tablets


**Brief Summary**

**ZIAC**™ (Bisoprolol Fumarate and Hydrochlorothiazide) Tablets

FOR FULL PRESCRIBING INFORMATION, PLEASE CONSULT PACKAGE INSERT.

**Description**

ZIAC® (bisoprolol fumarate and hydrochlorothiazide) is indicated for the treatment of hypertension. It combines two antihypertensive agents in a once-daily dose—a synthetic beta-1-selective (cardioselective) adrenergic blocking agent (bisoprolol fumarate) and a benzothiadiazine diuretic (hydrochlorothiazide).

**CLINICAL PHARMACOLOGY**

Plasma concentrations: ZIAC® tablets contain 2.5 mg of bisoprolol fumarate and 6.25 mg of hydrochlorothiazide. Hydrochlorothiazide is absorbed rapidly following oral administration. The peak plasma concentration occurs approximately 1 hour after oral administration. Bisoprolol fumarate is rapidly absorbed following oral administration. Peak plasma concentration occurs approximately 2 hours after oral administration. Bisoprolol fumarate is rapidly bioavailable following oral administration.

**Contraindications**

Patients Without a History of Cardiovascular Disease: Continued depression of the sodium-potassium pump is associated with a decrease in cardiac output and the sympathetic nervous system is excited. The effects of bisoprolol fumarate in patients with cardiovascular disease are not known.

**Warnings and Precautions**

Cardiovascular Disease: Beta-blockers should be used with caution in patients with cardiovascular disease. Patients with coronary artery disease, mitral valve prolapse, or congestive heart failure may be intolerant of beta-blockers. The effects of bisoprolol fumarate in patients with cardiovascular disease are not known.

**Adverse Reactions**

**Cardiovascular**

- Bradycardia
- Orthostatic hypotension
- Hypotension
- Hypertension
- Palpitations
- Arrhythmias
- Angina pectoris
- Chest pain
- Hypertension
- Chest pain
- Angina pectoris
- Hypertension
- Palpitations

**Respiratory**

- Dyspnea
- Coughing
- Asthma
- Bronchitis
- Respiratory tract infection
- Upper respiratory tract infection
- Rhinitis
- Nasal congestion

**Gastrointestinal**

- Diarrhea
- Nausea
- Vomiting
- Abdominal pain
- Constipation
- Flatulence
- Dyspepsia
- Gastritis

**Metabolic and Endocrine**

- Hypoglycemia
- Hyperglycemia
- Diabetes mellitus

**Musculoskeletal**

- Myalgia
- Arthritis
- Arthralgia
- Muscle cramps

**Psychiatric**

- Depression
- Anxiety
- Dizziness
- Paresthesia
- Restlessness

**General**

- Fatigue
- Tiredness
- Headache
- Insomnia

**Drug-Related Adverse Reactions**

**In Patients With and Without a History of Cardiovascular Disease**

**Body System**

<table>
<thead>
<tr>
<th>Adverse Experience</th>
<th>Placebo (N = 80)</th>
<th>ZIAC® (N = 80)</th>
</tr>
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<tbody>
<tr>
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<tr>
<td>Cardiovascular</td>
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<tr>
<td>Bradycardia</td>
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<td>0.7</td>
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<tr>
<td>Orthostatic hypotension</td>
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<tr>
<td>Hypotension</td>
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<tr>
<td>Hypertension</td>
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<tr>
<td>Palpitations</td>
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</tbody>
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**Summary**

ZIAC® is well tolerated in most patients. Most adverse effects (AEs) are mild and transient. In more than 60,000 patients treated worldwide with bisoprolol fumarate, occurrences of bronchospasm, asthma, and Rhutmann's syndrome were very rare. In the United States, 252 patients received bisoprolol fumarate 2.5, 5, 10, or 40 mg and hydrochlorothiazide 5, 10, or 25 mg (total dose) for 4 weeks. In Study 2, bisoprolol fumarate 2.5, 10, or 40 mg/6.25 mg was administered for 12 weeks. In 2013 patients, a total of 40,000 patients received bisoprolol fumarate 2.5, 5, 10, or 20 mg for 3 to 24 months.

**REFERENCES**


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Over 50% more analgesic power than the leading products in its class.

Well tolerated — Without aspirin-related side effects such as GI irritation and GI bleeding. The most frequent adverse reactions are drowsiness and dizziness.

Please see references and brief summary of full prescribing information on adjacent page.

*In most states.
ACULAR® (ketorolac tromethamine) 0.5%
Sterile Ophthalmic Solution

INDICATIONS AND USAGE
ACULAR® ophthalmic solution is indicated for the relief of ocular itching due to seasonal allergic conjunctivitis.

CONTRAINDICATIONS
ACULAR® ophthalmic solution is contraindicated in patients while wearing soft contact lenses and in patients with previously demonstrated hypersensitivity to any of the ingredients in the formulation.

WARNINGS
There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other nonsteroidal anti-inflammatory agents. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs. With some nonsteroidal anti-inflammatory drugs, there exists the potential for increased bleeding time due to interference with thromboocyte aggregation. There have been reports that ocular applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphemas) in conjunctival with ocular surgery.

PRECAUTIONS
It is recommended that ACULAR® ophthalmic solution be used with caution in patients with known bleeding tendencies or who are receiving medications which may prolong bleeding time.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: An 18-month study in mice at oral doses of ketorolac tromethamine equal to the per-enteral MRHD (Maximum Recommended Human Dose) and a 24-month study in rats at oral doses 2.5 times the perarental MRHD, showed no evidence of tumorigenicity. Ketorolac tromethamine was not mutagenic in Ames test, unscheduled DNA synthesis and repair, and in forward mutation assays. Ketorolac did not cause chromosome breakage in the in vivo mouse micro- nucleic assay. At 159o mg/ml (approximately 1000 times the average human plasma levels) and at higher concentrations ketorolac tromethamine increased the incidence of chromosomal aberrations in Chinese hamster ovary cells. Impairment of fertility did not occur in male or female rats at oral doses of 9 mg/kg (53.1 mg/m2) and 16 mg/kg (94.4 mg/m2) respectively.

Pregnancy: Pregnancy Category C. Reproduction studies have been performed in rabbits, using oral doses at 3.6 mg/kg (42.3 mg/m2) and in rats at 10 mg/kg (59 mg/m2) during organogenesis. Results of these studies did not reveal evidence of teratogenicity to the fetus. Oral doses of ketorolac tromethamine at 1.5 mg/kg (8.8 mg/m2), which was half of the human oral exposure, administered after gestation day 17 caused dysotocia and higher pup mortality in rats. There are no adequate and well-controlled studies in pregnant women. Ketorolac tromethamine should be used during pregnancy only if the potential benefit to the fetus justifies the potential risk to the fetus.

Nursing Mothers: Caution should be exercised when ACULAR® is administered to a nursing woman.

Pediatric Use: Safety and efficacy in children have not been established.

ADVERSE REACTIONS
In patients with allergic conjunctivitis, the most frequent adverse events reported were conjunctival redness, foreign body sensation, burning, stinging, irritation, itching, and lacrimation.

DRUG ABUSE AND DEPENDENCE
Abuse and dependence fatalities may be habit-forming.

Tolerance, psychological dependence, and physical dependence may occur following prolonged use of topical corticosteroids. The potential for the development of these conditions is usually a function of the duration of use and the frequency of administration, with the possibility of tolerance developing at the higher dosage levels. Physical dependence and psychological dependence to corticosteroids may not develop to the same extent, however, as with the more potent narcotics.

The untoward effects of the chronic use of topical corticosteroids may include suppression of the hypothalamic-pituitary-adrenal axis with the possibility of adrenocortical insufficiency in times of stress, atropine-like effects, including blurred vision, dry mouth, and nausea, and, at higher doses in the elderly, an increased risk of glaucoma.

In patients treated with ACULAR® ophthalmic solution, the incidence of cataracts was similar to control groups and was in the range of 5% to 10% in the US population.

Give allergic noses relief for itchy eyes due to seasonal allergic conjunctivitis.

When seasonal allergies strike, it's not just the nose they ambush. The eyes are fair game, too. In fact, 8 out of 10 patients with allergic noses also suffer from itchy eyes due to seasonal allergic conjunctivitis.

Stop the itch with ACULAR® Solution.

In a recent survey (n=272), the vast majority of responding patients confirmed that ACULAR® stopped their ocular itching quickly and effectively. Plus, ACULAR® has a favorable safety profile. There are no steroid-like side effects that can alter intraocular pressure, and no decongestant-like side effects, i.e., no risk to patients with narrow chamber angles.

So help rescue eyes from itching with ACULAR® the #1 prescribed ophthalmic preparation for the #1 patient complaint of seasonal allergic conjunctivitis — ocular itch. Because annoying antigens prey on more than just the nose.

The most frequently reported adverse events have been transient stinging and burning on instillation (approximately 40%). Not for use while wearing soft contact lenses.

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JABFP May-June 1995 Vol. 8 No. 3
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