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Benazepril (Lotensin)

??? ??????: 30 ??????/?????? 2017

Lotensin has been evaluated for safety in over 6000 patients with hypertension; over 700 of these patients were treated for at least one year. The overall incidence of reported adverse events was comparable in Lotensin and placebo patients.

The reported side effects were generally mild and transient, and there was no relation between side effects and age, duration of therapy, or total dosage within the range of 2 to 80 mg. Discontinuation of therapy because of a side effect was required in approximately 5% of U.S. patients treated with Lotensin and in 3% of patients treated with placebo.

).**Cough** ,**PRECAUTIONS** The most common reasons for discontinuation were headache (0.6%) and cough (0.5%) (see

The side effects considered possibly or probably related to study drug that occurred in U.S. placebo-controlled trials in more than 1% of patients treated with Lotensin are shown below.

PATIENTS IN U.S. PLACEBO-CONTROLLED STUDIES

	PLACEBO (N=496)		LOTENSIN (N=964)	
	%	N	%	N
Headache	4.2	21	6.2	60
Dizziness	2.4	12	3.6	35
Somnolence	0.4	2	1.6	15
Postural Dizziness	0.2	1	1.5	14

Other adverse experiences reported in controlled clinical trials (in less than 1% of benazepril patients or with less than 1% difference in incidence between benazepril or placebo treatment), and rarer events seen in post-marketing experience, include the following (in some, a causal relationship to drug use is uncertain):

Stevens-Johnson syndrome, pemphigus, apparent hypersensitivity reactions (manifested by dermatitis, pruritus, or rash), photosensitivity, and **Dermatologic:** flushing.

Nausea, pancreatitis, constipation, gastritis, vomiting, and melena. **Gastrointestinal:**

Thrombocytopenia and hemolytic anemia. **Hematologic:**

Anxiety, decreased libido, hypertonia, insomnia, nervousness, and paresthesia. **Neurologic and Psychiatric:**

Fatigue, asthma, bronchitis, dyspnea, sinusitis, urinary tract infection, frequent urination, infection, arthritis, impotence, alopecia, arthralgia, myalgia, asthenia, **Other:** sweating.

Another potentially important adverse experience, eosinophilic pneumonitis, has been attributed to other ACE inhibitors.

The adverse experience profile for pediatric patients appears to be similar to that seen in adult patients. **Pediatric Patients:**

Clinical Laboratory Test Findings

Decreases in hemoglobin (a low value and a decrease of 5 g/dL) were rare, occurring in only 1 of 2,014 patients receiving Lotensin alone and in 1 of **:*Hemoglobin***
1,357 patients receiving Lotensin plus a diuretic. No U.S. patients discontinued treatment because of decreases in hemoglobin.

) have been reported, as have **WARNINGS** Elevations of uric acid, blood glucose, serum bilirubin, and liver enzymes (see **:*Other (causal relationships unknown)***
scattered incidents of hyponatremia, electrocardiographic changes, eosinophilia, and proteinuria.