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Desloratadine (Clarinex)

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

The following adverse reactions are discussed in greater detail in other sections of the label:

-]**WARNINGS AND PRECAUTIONS** Hypersensitivity reactions. [See

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Adults and Adolescents

In multiple-dose placebo-controlled trials, 2834 patients ages 12 years or older received CLARINEX Tablets at doses of 2.5 mg to 20 mg daily, of **: *Allergic Rhinitis*** whom 1655 patients received the recommended daily dose of 5 mg. In patients receiving 5 mg daily, the rate of adverse events was similar between CLARINEX and placebo-treated patients. The percent of patients who withdrew prematurely due to adverse events was 2.4% in the CLARINEX group and 2.6% in the placebo group. There were no serious adverse events in these trials in patients receiving desloratadine. All adverse events that were reported by greater than or equal to 2% of patients who received the recommended daily dose of CLARINEX Tablets (5 mg once daily), and that were more common with CLARINEX Tablets than placebo, are listed in Table 1.

Table 1: Incidence of Adverse Events Reported by ? 2% of Adult and Adolescent Allergic Rhinitis Patients Receiving CLARINEX Tablets

Placebo (n=1652)	CLARINEX Tablets 5 mg (n=1655)	Adverse Event
		Infections and Infestations
2.0%	4.1%	Pharyngitis
		Nervous System Disorders
1.8%	2.1%	Somnolence
		Gastrointestinal Disorders
1.9%	3.0%	Dry Mouth
		Musculoskeletal and Connective Tissue Disorders
1.8%	2.1%	Myalgia
		Reproductive System and Breast Disorders
1.6%	2.1%	Dysmenorrhea
		General Disorders and Administration Site Conditions
1.2%	2.1%	Fatigue

The frequency and magnitude of laboratory and electrocardiographic abnormalities were similar in CLARINEX and placebotreated patients.

There were no differences in adverse events for subgroups of patients as defined by gender, age, or race.

In multiple-dose, placebo-controlled trials of chronic idiopathic urticaria, 211 patients ages 12 years or older received CLARINEX **:*Chronic Idiopathic Urticaria*** Tablets and 205 received placebo. Adverse events that were reported by greater than or equal to 2% of patients who received CLARINEX Tablets and that were more common with CLARINEX than placebo were (rates for CLARINEX and placebo, respectively): headache (14%, 13%), nausea (5%, 2%), fatigue (5%, 1%), dizziness (4%, 3%), pharyngitis (3%, 2%), dyspepsia (3%, 1%), and myalgia (3%, 1%).

Pediatrics

Two hundred and forty-six pediatric subjects 6 months to 11 years of age received CLARINEX Oral Solution for 15 days in three placebo-controlled clinical trials. Pediatric subjects aged 6 to 11 years received 2.5 mg once a day, subjects aged 1 to 5 years received 1.25 mg once a day, and subjects 6 to 11 months of age received 1.0 mg once a day.

In subjects 6 to 11 years of age, no individual adverse event was reported by 2 percent or more of the subjects.

In subjects 2 to 5 years of age, adverse events reported for CLARINEX and placebo in at least 2 percent of subjects receiving CLARINEX Oral Solution and at a frequency greater than placebo were fever (5.5%, 5.4%), urinary tract infection (3.6%, 0%) and varicella (3.6%, 0%).

In subjects 12 months to 23 months of age, adverse events reported for the CLARINEX product and placebo in at least 2 percent of subjects receiving CLARINEX Oral Solution and at a frequency greater than placebo were fever (16.9%, 12.9%), diarrhea (15.4%, 11.3%), upper respiratory tract infections (10.8%, 9.7%), coughing (10.8%, 6.5%), appetite increased (3.1%, 1.6%), emotional lability (3.1%, 0%), epistaxis (3.1%, 0%), parasitic infection (3.1%, 0%), pharyngitis (3.1%, 0%), rash maculopapular (3.1%, 0%).

In subjects 6 months to 11 months of age, adverse events reported for CLARINEX and placebo in at least 2 percent of subjects receiving CLARINEX Oral Solution and at a frequency greater than placebo were upper respiratory tract infections (21.2%, 12.9%), diarrhea (19.7%, 8.1%), fever (12.1%, 1.6%), irritability (12.1%, 11.3%), coughing (10.6%, 9.7%), somnolence (9.1%, 8.1%), bronchitis (6.1%, 0%), otitis media (6.1%, 1.6%), vomiting (6.1%, 3.2%), anorexia (4.5%, 1.6%), pharyngitis (4.5%, 1.6%), insomnia (4.5%, 0%), rhinorrhea (4.5%, 3.2%), erythema (3.0%, 1.6%), and nausea (3.0%, 0%).

There were no clinically meaningful changes in any electrocardiographic parameter, including the QTc interval. Only one of the 246 pediatric subjects receiving CLARINEX Oral Solution in the clinical trials discontinued treatment because of an adverse event.

Post-Marketing Experience

Because adverse events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The following spontaneous adverse events have been reported during the marketing of desloratadine: tachycardia, palpitations, rare cases of hypersensitivity reactions (such as rash, pruritus, urticaria, edema, dyspnea, and anaphylaxis), psychomotor hyperactivity, movement disorders (including dystonia, tics, and extrapyramidal symptoms), seizures, and elevated liver enzymes including bilirubin, and very rarely, hepatitis.