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Registration Information Inside!

Annual Meeting Program Edition

Join Us!

Program Highlights

Keynote Address—Captain Gene Cernan

Dialogue and Plenary Session Topics:

- Infections in Child (Day) Care: Managing the Dilemma
- Alternative Therapy in Neurology: You Want to Do What to Your Child?
- Environmental Hazards: What the Pediatrician Can Do

Seminars:

- Disorders That Mimic ADHD: Misdiagnosis of Attentional Problems
- Controversies and Updates in Pediatric Emergency Medicine
- School Epidemics: How Can the Pediatric Practitioner Help?

Selected Short Subjects:

- Massage Therapy for Infants and Children
- Seven Herbs Every Pediatrician Should Know
- Give It a Shot: Assessment of Immunization Practices in the Office

Workshops:

- Role Playing Your Most Difficult Patients and Situations
- Heart Sounds: Fearful Noise and Sweet Music
- The Pediatric Office of the Future: The Computer and You



Course descriptions and housing information enclosed

5 REASONS WHY YOU SHOULD ATTEND:

- Review and expand your knowledge and learn new skills and techniques
- Discuss your most challenging cases
- See the latest in medical products, services and equipment
- Earn valuable CME credits
- Enjoy New Orleans and its many attractions

Don't delay! Register by October 3 and save \$100.

New — Early Bird Special Bonus!
Register by September 19 and receive an exclusive AAP meeting tote bag.*

A voucher will appear in your advance registration packet if you are eligible.

*One per registration only.



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- **BIG convenience**
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 - Formulated without alcohol or dyes
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 - Lower cost-per-day than other branded prescription syrups*

In pediatric patients (6 to 11 years), most side effects were mild or moderate. The most common side effects included headache (11% at 5 mg, 14% at 10 mg, and 12.3% on placebo), pharyngitis (6.2% at 5 mg, 2.8% at 10 mg, and 2.9% on placebo), abdominal pain (4.4% at 5 mg, 5.6% at 10 mg, and 1.9% on placebo), and somnolence (1.9% at 5 mg, 4.2% at 10 mg, and 1.3% on placebo). Discontinuation due to side effects was not significantly different from placebo (0.4% for ZYRTEC syrup vs 1.0% for placebo).

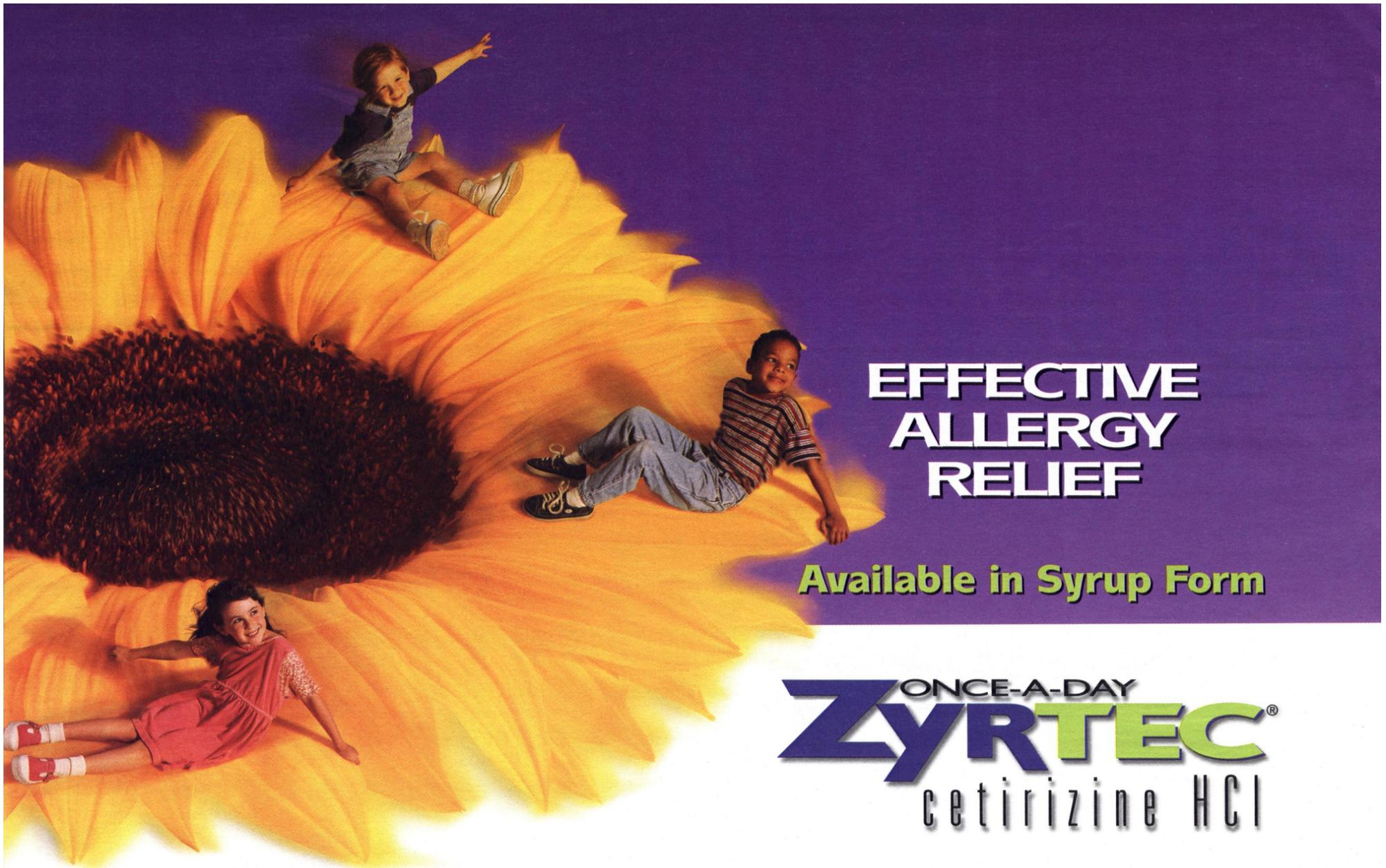
EFFECTIVE ALLERGY RELIEF



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Please see brief summary for ZYRTEC tablets and syrup on adjacent page.

*Based on a comparison of the list price to wholesalers (wholesale acquisition cost of ZYRTEC syrup and Claritin syrup); *Medi-span*, March 1997. Actual cost to patients may vary.



EFFECTIVE ALLERGY RELIEF

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Due caution should be exercised when driving a car or operating potentially dangerous machinery.

BRIEF SUMMARY

ZYRTEC[®] (CETIRIZINE HYDROCHLORIDE) TABLETS AND SYRUP FOR ORAL USE (FOR FULL PRESCRIBING INFORMATION, CONSULT PACKAGE INSERT)

INDICATIONS AND USAGE **Seasonal Allergic Rhinitis:** ZYRTEC is indicated for the relief of symptoms associated with seasonal allergic rhinitis due to allergens such as ragweed, grass and tree pollens in adults and children 6 years of age and older. Symptoms treated effectively include sneezing, rhinorrhea, nasal pruritus, ocular pruritus, tearing and redness of the eyes. **Perennial Allergic Rhinitis:** ZYRTEC is indicated for the relief of symptoms associated with perennial allergic rhinitis due to allergens such as dust mites, animal dander and molds in adults and children 6 years of age and older. Symptoms treated effectively include sneezing, rhinorrhea, postnasal discharge, nasal pruritus, ocular pruritus and tearing. **Chronic Urticaria:** ZYRTEC is indicated for the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age and older. It significantly reduces the occurrence, severity and duration of hives and significantly reduces pruritus.

CONTRAINDICATIONS ZYRTEC is contraindicated in those patients with a known hypersensitivity to it or any of its ingredients or hydroxyzine. **PRECAUTIONS** **Activities Requiring Mental Alertness:** In clinical trials, the occurrence of somnolence has been reported in some patients taking ZYRTEC; due caution should therefore be exercised when driving a car or operating potentially dangerous machinery. Concurrent use of ZYRTEC with alcohol or other CNS depressants should be avoided because additional reductions in alertness and additional impairment of CNS performance may occur. **Drug-drug Interactions:** No clinically significant drug interactions have been found with theophylline at a low dose, azithromycin, pseudoephedrine, ketoconazole, or erythromycin. There was a small decrease in the clearance of cetirizine caused by a 400 mg dose of theophylline; it is possible that larger theophylline doses could have a greater effect. **Carcinogenesis, Mutagenesis and Impairment of Fertility:** No evidence of carcinogenicity was observed in a 2-year carcinogenicity study in rats at dietary doses up to 20 mg/kg/day (approximately 10 times the maximum recommended human daily oral dose on a mg/m² basis). An increased incidence of benign liver tumors was found in a 2-year carcinogenicity study in male mice at a dietary dose of 16 mg/kg/day (approximately 4 times the maximum recommended human daily oral dose on a mg/m² basis). The clinical significance of these findings during long-term use of ZYRTEC is not known. Cetirizine was not mutagenic in the Ames test, and not clastogenic in the human lymphocyte assay, the mouse lymphoma assay, and *in vivo* micronucleus test in rats. No impairment of fertility was found in a fertility and general reproductive performance study in mice at an oral dose of 64 mg/kg/day (approximately 26 times the maximum recommended adult human daily oral dose on a mg/m² basis). **Pregnancy Category B:** Cetirizine was not teratogenic in mice, rats and rabbits at oral doses up to 96, 225, and 135 mg/kg/day (or approximately 40, 180, and 215 times the maximum recommended adult human daily oral dose on a mg/m² basis), respectively. There are no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human response, ZYRTEC should be used in pregnancy only if clearly needed. **Nursing Mothers:** Retarded pup weight gain was found in mice during lactation when dams were given cetirizine at 96 mg/kg/day (approximately 40 times the maximum recommended adult human daily oral dose on a mg/m² basis). Studies in beagle dogs indicate that approximately 3% of the dose is excreted in milk. Cetirizine has been reported to be excreted in human breast milk. Because many drugs are excreted in human milk, use of ZYRTEC in nursing mothers is not recommended. **Geriatric Use:** In placebo-controlled trials, 186 patients aged 65 to 94 years received doses of 5 to 20 mg of ZYRTEC per day. Adverse events were similar in this group to patients under age 65. Subset analysis of efficacy in this group was not done.

Pediatric Use: The safety of ZYRTEC, at daily doses of 5 or 10 mg, has been demonstrated in 376 pediatric patients 6-11 years of age in placebo-controlled trials lasting up to four weeks and in 254 patients in a non-placebo-controlled 12 week trial. *The effectiveness of ZYRTEC for the treatment of seasonal and perennial allergic rhinitis and chronic idiopathic urticaria in this pediatric age group is based on an extrapolation of the demonstrated efficacy of ZYRTEC in adults in these conditions and the likelihood that the disease course, pathophysiology and the drug's effect are substantially similar between these two populations.* The recommended doses for the pediatric population are based on a cross-study comparison of the pharmacokinetics and pharmacodynamics of cetirizine in adults and pediatric subjects and on the safety profile of cetirizine in both adults and pediatric patients at doses equal to or higher than the recommended doses. The cetirizine AUC and C_{max} in pediatric subjects 6-11 years of age who received a single dose of 10 mg of cetirizine syrup was estimated to be intermediate between that observed in adults who received a single dose of 10 mg of cetirizine tablets and those who received a single dose of 20 mg of cetirizine tablets. **ADVERSE REACTIONS** Controlled and uncontrolled clinical trials conducted in the United States and Canada included more than 6000 patients aged 12 years and older, with more than 3900 receiving ZYRTEC at doses of 5 to 20 mg per day. The duration of treatment ranged from 1 week to 6 months, with a mean exposure of 30 days. Most adverse reactions reported during therapy with ZYRTEC were mild or moderate. In placebo-controlled trials, the incidence of discontinuations due to adverse reactions in patients receiving ZYRTEC 5 mg or 10 mg was not significantly different from placebo (2.9% vs. 2.4%, respectively). The most common adverse reaction in patients aged 12 years and older that occurred more frequently on ZYRTEC than placebo was somnolence. The incidence of somnolence associated with ZYRTEC was dose related, 6% in placebo, 11% at 5 mg and 14% at 10 mg. Discontinuations due to somnolence for ZYRTEC were uncommon (1.0% on ZYRTEC vs. 0.6% on placebo). Fatigue and dry mouth also appeared to be treatment-related adverse reactions. There were no differences by age, race, gender or by body weight with regard to the incidence of adverse reactions. Table 1 lists adverse experiences in patients aged 12 years and older which were reported for ZYRTEC 5 and 10 mg in controlled clinical trials in the United States and that were more common with ZYRTEC than placebo. **Table 1. Adverse Experiences Reported in Patients aged 12 years and older in Placebo-Controlled United States ZYRTEC Trials (Maximum Dose of 10 mg) at Rates of 2% or Greater (Percent Incidence), ZYRTEC (N=2034) vs Placebo (N=1612) respectively:** Somnolence (13.7% vs 6.3%); Fatigue (5.9% vs 2.6%); Dry Mouth (5.0% vs 2.3%); Pharyngitis (2.0% vs 1.9%); Dizziness (2.0% vs 1.2%). In addition, headache and nausea occurred in more than 2% of the patients, but were more common in placebo patients. Pediatric studies were also conducted with ZYRTEC. More than 1300 pediatric patients (6 to 11 years) with more than 900 treated with ZYRTEC at doses of 1.25 to 10 mg per day were included in controlled and uncontrolled clinical trials conducted in the United States. The duration of treatment ranged from 2 to 12 weeks. The majority of reported adverse reactions reported in pediatric patients (6 to 11 years) with ZYRTEC were mild or moderate. In placebo-controlled trials, the incidence of discontinuations due to adverse reactions in pediatric patients receiving up to ZYRTEC 10 mg was uncommon

(0.4% on ZYRTEC vs. 1.0% on placebo). Table 2 lists adverse experiences which were reported for ZYRTEC 5 and 10 mg in pediatric patients (6 to 11 years) in placebo-controlled clinical trials in the United States and were more common with ZYRTEC than placebo. Of these, abdominal pain was considered treatment-related and somnolence appeared to be dose-related, 1.3% in placebo, 1.9% at 5 mg and 4.2% at 10 mg. **Table 2. Adverse Experiences Reported in Pediatric Patients (6 to 11 years) in Placebo-Controlled United States ZYRTEC Trials (5 or 10 mg dose) Which Occurred at a Frequency of ≥ 2% in Either the 5 mg or the 10 mg ZYRTEC Group, and More Frequently Than in the Placebo Group. ZYRTEC 5 mg (N=161), 10 mg (N=215) vs Placebo (N=309):** Headache (11.0%, 5 mg; 14.0%, 10 mg; 12.3%, placebo); Pharyngitis (6.2%, 5 mg; 2.8%, 10 mg; 2.9%, placebo); Abdominal pain (4.4%, 5 mg; 5.6%, 10 mg; 1.9%, placebo); Coughing (4.4%, 5 mg; 2.8%, 10 mg; 3.9%, placebo); Somnolence (1.9%, 5 mg; 4.2%, 10 mg; 1.3%, placebo); Diarrhea (3.1%, 5 mg; 1.9%, 10 mg; 1.3%, placebo); Epistaxis (3.7%, 5 mg; 1.9%, 10 mg; 2.9%, placebo); Bronchospasm (3.1%, 5 mg; 1.9%, 10 mg; 1.9%, placebo); Nausea (1.9%, 5 mg; 2.8%, 10 mg; 1.9%, placebo); Vomiting (2.5%, 5 mg; 2.3%, 10 mg; 1.0%, placebo). The following events were observed infrequently (less than 2%), in either 3982 adults and children 12 years and older or in 659 pediatric (6 to 11 years) patients who received ZYRTEC in U.S. trials, including an open adult study of six months duration; a causal relationship with ZYRTEC administration has not been established. **Autonomic Nervous System:** anorexia, urinary retention, flushing, increased salivation, dry mouth. **Cardiovascular:** palpitation, tachycardia, hypertension, cardiac failure. **Central and Peripheral Nervous Systems:** paresthesia, confusion, hyperkinesia, hypertonia, migraine, tremor, vertigo, leg cramps, ataxia, dysphonia, abnormal coordination, hyperesthesia, hypoesthesia, myelitis, paralysis, ptosis, twitching, visual field defect, syncope, dizziness. **Gastrointestinal:** increased appetite, dyspepsia, abdominal pain, diarrhea, flatulence, constipation, vomiting, ulcerative stomatitis, aggravated tooth caries, stomatitis, tongue discoloration, tongue edema, gastritis, rectal hemorrhage, hemorrhoids, melena, abnormal hepatic function, eructation. **Genitourinary:** polyuria, urinary tract infection, cystitis, dysuria, hematuria, micturition frequency, urinary incontinence. **Hearing and Vestibular:** earache, tinnitus, deafness, ototoxicity. **Metabolic/Nutritional:** thirst, dehydration, diabetes mellitus. **Musculoskeletal:** myalgia, arthralgia, arthrosis, arthritis, muscle weakness. **Psychiatric:** insomnia, sleep disorder, nervousness, depression, emotional lability, impaired concentration, anxiety, depersonalization, paranoia, abnormal thinking, agitation, amnesia, decreased libido, euphoria. **Respiratory System:** epistaxis, rhinitis, coughing, bronchospasm, dyspnea, upper respiratory tract infection, hyperventilation, sinusitis, increased sputum, bronchitis, pneumonia, respiratory disorder. **Reproductive:** dysmenorrhea, female breast pain, intermenstrual bleeding, leukorrhea, menorrhagia, vaginitis. **Reticuloendothelial:** lymphadenopathy. **Skin:** pruritus, rash, dry skin, urticaria, acne, dermatitis, erythematous rash, increased sweating, alopecia, angioedema, furunculosis, bullous eruption, eczema, hyperkeratosis, hypertrichosis, photosensitivity reaction, photosensitivity toxic reaction, maculopapular rash, seborrhea, purpura, skin disorder, skin nodule. **Special Senses:** taste perversion, taste loss, parosmia. **Vision:** blindness, loss of accommodation, eye pain, conjunctivitis, xerophthalmia, glaucoma, ocular hemorrhage. **Body as a Whole:** Increased weight, back pain, malaise, fever, asthenia, generalized edema, periorbital edema, peripheral edema, rigors, leg edema, face edema, hot flashes, enlarged abdomen, nasal polyp, pain, pallor, chest pain, accidental injury. Occasional instances of transient, reversible hepatic transaminase elevations have occurred during cetirizine therapy. A single case of possible drug-induced hepatitis with significant transaminase elevation (500 to 1000 IU/L) and elevated bilirubin has been reported. In foreign marketing experience the following additional rare, but potential severe adverse events have been reported: hemolytic anemia, thrombocytopenia, orofacial dyskinesia, severe hypotension, anaphylaxis, hepatitis, glomerulonephritis, stillbirth, and cholestasis. **DRUG ABUSE AND DEPENDENCE** There is no information to indicate that abuse or dependency occurs with ZYRTEC. **OVERDOSAGE** Overdose has been reported with ZYRTEC. In one adult patient who took 150 mg of ZYRTEC, the patient was somnolent but did not display any other clinical signs or abnormal blood chemistry or hematology results. In an 18-month-old pediatric patient who took an overdose of ZYRTEC (approximately 180 mg), restlessness and irritability were observed initially; this was followed by drowsiness. Should overdose occur, treatment should be symptomatic or supportive, taking into account any concomitantly ingested medications. There is no known specific antidote to ZYRTEC. ZYRTEC is not effectively removed by dialysis, and dialysis will be ineffective unless a dialyzable agent has been concomitantly ingested. The acute minimal lethal oral doses in mice and rats were 237 and 562 mg/kg, respectively (approximately 55 and 265 times the maximum recommended human daily oral dose on a mg/m² basis). In rodents, the target of acute toxicity was the central nervous system, and the target of multiple-dose toxicity was the liver. **DOSAGE AND ADMINISTRATION** **Adults and Children 12 years and older:** The recommended initial dose of ZYRTEC is 5 or 10 mg per day in adults and children 12 years and older, depending on symptom severity. Most patients in clinical trials started at 10 mg. ZYRTEC is given as a single daily dose, with or without food. The time of administration may be varied to suit individual patient needs. In patients with decreased renal function (creatinine clearance 11-31 mL/min), patients on hemodialysis (creatinine clearance less than 7 mL/min), and in hepatically impaired patients, a dose of 5 mg once daily is recommended. **Children 6 to 11 years:** The recommended initial dose of ZYRTEC in children aged 6 to 11 years is 5 or 10 mg (1 or 2 teaspoons) once daily depending on symptom severity. The time of administration may be varied to suit individual patient needs. **HOW SUPPLIED** ZYRTEC[®] tablets are white, film-coated, rounded-off rectangular shaped containing 5 mg or 10 mg cetirizine hydrochloride. 5 mg tablets are engraved with "ZYRTEC" on one side and with "550" on the other. Bottles of 100; NDC 0069-5500-66. 10 mg tablets are engraved with "ZYRTEC" on one side and with "551" on the other. Bottles of 100; NDC 0069-5510-66. **STORAGE:** Store at room temperature 59° to 86°F (15° - 30°C). ZYRTEC[®] syrup is colorless to slightly yellow with a banana-grape flavor. Each teaspoonful (5 mL) contains 5 mg cetirizine hydrochloride. ZYRTEC[®] syrup is supplied as follows: 120 mL amber glass bottles, NDC 0069-5530-47

1 pint amber glass bottles, NDC 0069-5530-93

STORAGE: Store at 41° to 86°F (5° - 30°C). Cetirizine is licensed from UCB Pharma, Inc.

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