Zyrtec® (cetirizine HCl) is effective relief for your pediatric patients. Zyrtec is available in a "child-friendly," pleasant-tasting syrup that makes your choice for effective allergy relief even easier. Zyrtec offers BIG advantages:

• EFFECTIVE symptomatic relief
  - Seasonal and perennial allergic rhinitis and chronic idiopathic urticaria

• BIG convenience
  - Once-a-day dosing

• BIG taste
  - Pleasant-tasting, banana-grape flavored syrup
  - Formulated without alcohol or dyes

• BIG value
  - 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).

*Based on a comparison of the list price to wholesaler's wholesale acquisition cost of Zyrtec syrup and Claritin syrup. Medi-Span®, March 1997. Actual cost to patients may vary.
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 (See PRECAUTIONS 16.4: PREGNANCY FOR INTRAUTERINE USE).

**INDICATIONS AND USAGE**
Seasonal Allergic Rhinitis: ZYRTEC* is indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 6 years of age and older. Symptoms such as sneezing, rhinorrhea, nasal congestion, and itchy, red, or watery eyes often occur during the cold or allergy season. ZYRTEC* is for improvement of these symptoms.

Concomitant Use of ZYRTEC* with certain antihistamines, decongestants, stimulants, or CNS depressants (e.g., barbiturates, alcohol, and nonprescription medications) may result in CNS depression. The use of ZYRTEC* concurrently with alcohol or other CNS depressants is not recommended.

**CONTRAINDICATIONS**
ZYRTEC* is contraindicated in patients who are hypersensitive to cetirizine or any of its components or to hydroxyzine.

**PRECAUTIONS**
Alertness
In clinical trials, the incidence of somnolence has been reported in some patients taking ZYRTEC*. Hence, it should be used with caution in patients with diseases in which the degree of mental alertness is important (e.g., patients in high-speed motor vehicle, railway, or aircraft travel). ZYRTEC* should be administered with caution to children under 6 years of age, or to those with mild CNS depression. ZYRTEC* should be given with caution to patients with a history of allergic reactions to cetirizine or to other members of the histamine, amine, or pseudoephedrine class. ZYRTEC* should be used with caution to patients with severe hepatic insufficiency or with known or suspected liver disease. Severe hepatic insufficiency may interfere with the metabolism and excretion of ZYRTEC*.

**ADVERSE REACTIONS**
1. In general, adverse reactions reported with ZYRTEC* have been mild or moderate and have not usually required withdrawal of therapy. Most reactions have occurred during the first 2 to 6 months of treatment. 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 ZYRTEC* 10 mg was not significantly different from placebo (2.9% vs 2.4%, respectively).

2. The most common adverse reactions observed in patients aged 12 years and older that occurred more frequently on ZYRTEC* than placebo included headache (1.9% vs 1.0%), abdominal pain (0.8% vs 0.6%), fatigue (0.5% vs 0.4%), vomiting (0.2% vs 0.1%), dry mouth (5.0% vs 2.3%), pharyngitis (0.2% vs 0.1%). Headache and response to headache occurred more often than in placebo patients. These reactions were not different from age, race, gender or body weight with regard to the incidence of adverse reactions. Table 1 lists adverse reactions in patients aged 12 years and older who were reported with ZYRTEC* 10 mg and 15 mg in controlled clinical trials in the United States and those that were more common with ZYRTEC* than placebo.

3. Table 1. Adverse Experiences Reported in Patients Aged 12 years and older in Placebo-Controlled United States ZYRTEC* Trials (Maximum Dose of 15 mg) at Rates of 2% or Greater (Percent Incidence).

4. The adverse reactions associated with ZYRTEC* in children 6 years of age and older were generally similar to those seen in adults. The adverse reactions were limited to the safety population (n=2034) and were evaluated in ZYRTEC* 10 mg (N=967) and Placebo (N=1067) groups. The most common adverse reactions reported by children 6 years of age and older were those that were also reported by adults. Table 2 lists adverse reactions in patients aged 6 years and older who were reported with ZYRTEC* 10 mg and 15 mg in controlled clinical trials in the United States and those that were more common with ZYRTEC* than placebo.

5. Table 2. Adverse Experiences Reported in Pediatric Patients (6 to 11 years) in Placebo-Controlled United States ZYRTEC* Trials (Maximum Dose of 15 mg) at Rates of 2% or Greater than Placebo (0.5% vs 0.4% and 2.4% vs 2.0%).

6. The adverse reactions associated with ZYRTEC* in patients with a known hypersensitivity to cetirizine or any of its components, or to hydroxyzine or other members of the histamine, amine, or pseudoephedrine class, have been limited to the safety population (N=2034) and were evaluated in ZYRTEC* 10 mg (N=961) and Placebo (N=1063) groups. The most common adverse reactions reported by pediatric patients aged 6 years of age and older were those that were also reported by adults. Table 3 lists adverse reactions in patients aged 6 years and older who were reported with ZYRTEC* 10 mg and 15 mg in controlled clinical trials in the United States and those that were more common with ZYRTEC* than placebo.

7. Table 3. Adverse Experiences Reported in Pediatric Patients Aged 6 Years and older in Placebo-Controlled United States ZYRTEC* Trials (Maximum Dose of 15 mg) at Rates of 3% or Greater than Placebo (0.5% vs 0.4%)

8. The adverse reactions associated with ZYRTEC* in patients with a known hypersensitivity to cetirizine or any of its components, or to hydroxyzine or other members of the histamine, amine, or pseudoephedrine class, have been limited to the safety population (N=2034) and were evaluated in ZYRTEC* 10 mg (N=961) and Placebo (N=1063) groups. The most common adverse reactions reported by pediatric patients aged 6 years of age and older were those that were also reported by adults. Table 4 lists adverse reactions in patients aged 6 years and older who were reported with ZYRTEC* 10 mg and 15 mg in controlled clinical trials in the United States and those that were more common with ZYRTEC* than placebo.

9. Table 4. Adverse Experiences Reported in Pediatric Patients Aged 6 Years and older in Placebo-Controlled United States ZYRTEC* Trials (Maximum Dose of 15 mg) at Rates of 3% or Greater than Placebo (0.5% vs 0.4%)

10. The adverse reactions associated with ZYRTEC* in patients with a known hypersensitivity to cetirizine or any of its components, or to hydroxyzine or other members of the histamine, amine, or pseudoephedrine class, have been limited to the safety population (N=2034) and were evaluated in ZYRTEC* 10 mg (N=961) and Placebo (N=1063) groups. The most common adverse reactions reported by pediatric patients aged 6 years of age and older were those that were also reported by adults. Table 5 lists adverse reactions in patients aged 6 years and older who were reported with ZYRTEC* 10 mg and 15 mg in controlled clinical trials in the United States and those that were more common with ZYRTEC* than placebo.