I

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

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).

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.
**BRIEF SUMMARY**

ZYRTEC (cetirizine hydrochloride) tablets and syrup for oral use (FULL PRECAUTIONS, CONSENT PACKAGE INSERT)

**INDICATIONS AND USAGE**

Seasonal Allergic Rhinitis: ZYRTEC is indicated for the relief of symptoms associated with seasonal allergic rhinitis due to allergic reactions such as sneezing, running, and sneezing, itching of the eyes, nose, and throat and redness of the eyes.

**CONTRAINDICATIONS**

ZYRTEC is contraindicated in patients who have a known hypersensitivity to it or any of its ingredients.

**PRECAUTIONS**

**Activity 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.

**Drug Interactions:** Cetirizine is not a clinically significant inhibitor or inducer of the cytochrome P450 isozymes CYP1A2, CYP2C9, CYP2C19, CYP2D6, or CYP3A4.

**Adverse Reactions**

**Table 1: Adverse Experiences Reported in Pediatric Patients (6 to 11 years) in Placebo-Controlled Clinical Trials**

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo</th>
<th>ZYRTEC 2.5 mg</th>
<th>ZYRTEC 5 mg</th>
<th>ZYRTEC 10 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>0.0%</td>
<td>4.2%</td>
<td>7.2%</td>
<td>8.6%</td>
</tr>
<tr>
<td>Drowsiness</td>
<td>0.0%</td>
<td>3.7%</td>
<td>5.8%</td>
<td>9.1%</td>
</tr>
<tr>
<td>Nausea</td>
<td>0.0%</td>
<td>0.5%</td>
<td>1.2%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>0.0%</td>
<td>0.5%</td>
<td>1.2%</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

**Special Senses**

Table 2: Transaminases (ALT, AST, and Bilirubin), Liver and Other Laboratory Test Results

**Special Senses**

Table 3: Other Laboratory Test Results

**Summary of Other Clinical Experience**

**Special Senses**

Table 4: Transaminases (ALT, AST, and Bilirubin), Liver and Other Laboratory Test Results

**Special Senses**

Table 5: Other Laboratory Test Results

**Special Senses**

Table 6: Transaminases (ALT, AST, and Bilirubin), Liver and Other Laboratory Test Results

**Special Senses**

Table 7: Other Laboratory Test Results

**Special Senses**

Table 8: Transaminases (ALT, AST, and Bilirubin), Liver and Other Laboratory Test Results

**Special Senses**

Table 9: Other Laboratory Test Results

**Special Senses**

Table 10: Transaminases (ALT, AST, and Bilirubin), Liver and Other Laboratory Test Results

**Special Senses**

Table 11: Other Laboratory Test Results

**Special Senses**

Table 12: Transaminases (ALT, AST, and Bilirubin), Liver and Other Laboratory Test Results

**Special Senses**

Table 13: Other Laboratory Test Results

**Special Senses**

Table 14: Transaminases (ALT, AST, and Bilirubin), Liver and Other Laboratory Test Results

**Special Senses**

Table 15: Other Laboratory Test Results

**Special Senses**

Table 16: Transaminases (ALT, AST, and Bilirubin), Liver and Other Laboratory Test Results

**Special Senses**

Table 17: Other Laboratory Test Results

**Special Senses**

Table 18: Transaminases (ALT, AST, and Bilirubin), Liver and Other Laboratory Test Results

**Special Senses**

Table 19: Other Laboratory Test Results

**Special Senses**

Table 20: Transaminases (ALT, AST, and Bilirubin), Liver and Other Laboratory Test Results

**Special Senses**

Table 21: Other Laboratory Test Results

**Special Senses**

Table 22: Transaminases (ALT, AST, and Bilirubin), Liver and Other Laboratory Test Results

**Special Senses**

Table 23: Other Laboratory Test Results

**Special Senses**

Table 24: Transaminases (ALT, AST, and Bilirubin), Liver and Other Laboratory Test Results

**Special Senses**

Table 25: Other Laboratory Test Results

**Special Senses**

Table 26: Transaminases (ALT, AST, and Bilirubin), Liver and Other Laboratory Test Results

**Special Senses**

Table 27: Other Laboratory Test Results

**Special Senses**

Table 28: Transaminases (ALT, AST, and Bilirubin), Liver and Other Laboratory Test Results

**Special Senses**

Table 29: Other Laboratory Test Results

**Special Senses**

Table 30: Transaminases (ALT, AST, and Bilirubin), Liver and Other Laboratory Test Results

**Special Senses**

Table 31: Other Laboratory Test Results

**Effective Allergy Relief**

Available in Syrup Form

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