



**AFORVIR SYRUP**  
**Product Information Sheet**

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| <b>Generic Name</b>                        | Cetirizine Hydrochloride   |
| <b>FDA Classification</b>                  | Over-the-Counter (OTC) Drug  |
| <b>Formulation</b>                         | Each film-coated tablet contains:<br>Cetirizine Hydrochloride BP.....10mg  |
| <b>Preparation</b>                         | Tablet   |
| <b>Therapeutic Class</b>                   | Antihistamine  |
| <b>Indication</b>                          | In adults and pediatric patients 6 years old and above: <ul style="list-style-type: none"><li>• Cetirizine is indicated for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis</li><li>• Cetirizine is indicated for the relief of symptoms of chronic idiopathic urticaria</li></ul>   |
| <b>Dosage and Method of Administration</b> | <p>Cetirizine hydrochloride is given orally at 10mg per day or 5 mg twice a day for adults and children 6 years and older. There was no additional benefit seen in increasing dose of cetirizine hydrochloride to 20 mg.</p> <p>In children 2 to 5 years, cetirizine hydrochloride may be given at 5 mg per day given as one dose or 2.5 mg twice a day given every after 12 hours.</p> <p>For children ages 6 months to 2 years with perennial allergic rhinitis and chronic urticaria, the initial dose is 2.5 mg per day. This may be increased to a maximum of 5 mg per day give two times per day.</p> <p>Or as prescribed by the physician.</p> <p>For patients with hepatic and renal impairment, the dose should be reduced to half their usual dose per day.</p> <p>In managing seasonal rhinitis, it is recommended that cetirizine hydrochloride be given at the beginning of hay fever season when pollens are still few.</p> <p>Cetirizine hydrochloride may be administered with or without food as it will not affect absorption of the drug.</p> |



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| <p><b>Mechanism of Action</b></p> | <p>Cetirizine hydrochloride is a long-acting antihistamine causing little or no drowsiness. It does not demonstrate any antimuscarinic activity. This drug competes reversibly with histamines which are released from mast cells. Once bound to H1 receptor sites in the tissues, cetirizine inhibits histamine-induced allergic reactions by blocking eosinophil infiltration to the site of allergen-induced cutaneous reactions.</p>   |
| <p><b>Pharmacokinetics</b></p>    | <p>Upon oral administration, cetirizine hydrochloride is rapidly absorbed from gastrointestinal tract. Peak plasma concentration is achieved after an hour of Cmax of the drug may be delayed by food. However, it does not change the amount of drug absorbed. It has higher affinity to peripheral rather than central histamine H1 receptors and does not penetrate the blood-brain barrier to a significant extent.</p> <p>Cetirizine hydrochloride is highly protein bound (93%) and has half-life of approximately 11 hours in adults. This is mainly excreted in the urine as unchanged drug.</p> <p>Cetirizine has been detected in breast milk.</p> |
| <p><b>Contraindication</b></p>    | <p>Cetirizine hydrochloride is contraindicated to those who are allergic to cetirizine hydroxyzine or any component of the formulation.</p> <p>Cetirizine hydrochloride is not recommended to be given to hypokalemia patients with chronic renal failure undergoing hemodialysis (see Overdose).</p> <p>It should not be given to children with hepatic and renal impairment, who are younger than 6 years of age.</p>  |
| <p><b>Special Precaution</b></p>  | <p>Cetirizine hydrochloride should be used with caution in patients who requires mental alertness or physical coordination in their work such as drivers or machine operators since it may cause drowsiness.</p> <p><i>Use of Pregnant Women</i></p> <p>No data is available on the safety of administration of cetirizine hydrochloride in pregnant women apart from an animal study which reveals absence of teratogenicity. As such, cetirizine hydrochloride must be given to pregnant patients only when necessary.</p>   |



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|                                 | <p><i>Use in Lactating Mothers</i><br/>Cetirizine hydrochloride is excreted in breast milk. Thus use in lactating mothers is not recommended.</p> <p><i>Use in Infants</i><br/>Infants and children must not be given cetirizine hydrochloride as this may increase risk of experiencing antimuscarinic effects.</p> <p><i>Use in Elderly Patients</i><br/>Cetirizine hydrochloride must be used with caution in elderly patients who most likely have impaired renal and hepatic function. Since the drug is metabolized through the renal mechanism half-life of cetirizine hydrochloride in such patients will be prolonged. Dose of the drug must be reduced in elderly patients.</p>   |
| <p><b>Adverse Reactions</b></p> | <p>Cetirizine hydrochloride, though considered as non-sedating antihistamine, was found to cause drowsiness.</p> <p>Recurrent acute hepatitis developed in one patient taking cetirizine hydrochloride for control of seasonal allergic rhinitis.</p> <p>Other adverse effects associated with the use of cetirizine hydrochloride are irritability, insomnia, somnolence, fatigue, dry mouth, pharyngitis, dizziness, headache, abdominal pain, cough, diarrhea, epistaxis, bronchospasm, nausea and vomiting and hypersensitivity manifested by urticaria and fixed drug eruptions.</p> <p>Although cetirizine hydrochloride has low potential for severe hepatotoxicity, the possibility of developing autoimmune-mediated hepatotoxicity should be considered when administering the drug. A patient under long-term treatment with cetirizine hydrochloride for atopic dermatitis was reported to have developed life-threatening hepatitis.</p> |
| <p><b>Overdosage</b></p>        | <p>Overdosage of cetirizine hydrochloride (180mg) caused restlessness, irritability and drowsiness in an 18-month old child. In adults, drowsiness, upon ingestion of 150 mg cetirizine hydrochloride, has been reported.</p> <p>A case of a hypokalemic dialyzed patient with chronic renal failure, was reported to develop symptomatic episodes of torsades de pointes after overdosage with cetirizine hydrochloride.</p>   |



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| <b>Drug Interaction</b>            | <p>Sedation may be enhanced upon concomitant use of antihistamines in general with central nervous system depressants such as barbiturates, alcohol, hypnotic, opioid analgesics, anxiolytic sedatives and neuroleptics.</p> <p>The use of cetirizine hydrochloride with drugs that inhibit the cytochrome P-450 microsomal enzymes such as azithromycin, erythromycin and ketoconazole, did not cause clinically significant changes.</p> <p>Effects of alcohol and other CNS depressants are enhanced by cetirizine hydrochloride.</p> <p>Pharmacokinetics properties of ritonavir, HIV protease inhibitor, are not affected by cetirizine hydrochloride.</p> |
| <b>Storage Condition</b>           | Store at temperatures not exceeding 30C.  |
| <b>Availability</b>                | 60 mL Amber Bottle, Syrup   |
| <b>Suggested Retail Price</b>      | Php 264.00  |
| <b>Manufacturer</b>                | <b>Microlabs/India</b>  |
| <b>Distributor/ Subdistributor</b> | Zuellig Pharma Corporation  |