# Simtec

**Cetirizine Hydrochloride 10mg**

**PRODUCT DESCRIPTION**
A white to off-white oval shape film coated tablet with a break line on one side and embossed with 'UP' on the other side.

**COMPOSITION**
Each tablet contains 10mg of Cetirizine Hydrochloride.

**PHARMACODYNAMICS**
Cetirizine, a piperazine derivative, is a potent histamine $H_1$ receptor antagonist. It is reported to be long acting and with some mast-cell stabilizing activity. Cetirizine is claimed to have a low potential for drowsiness in usual doses and to be virtually free of antimuscarinic activity.

**PHARMACOKINETICS**
Cetirizine is rapidly absorbed from the gastro-intestinal tract after oral administration. Food may delay the rate of absorption but not the extent of Cetirizine absorption. Peak plasma concentration is attained in about one hour. The extent of distribution into human breast milk is unknown. Cetirizine is about 93% bound to plasma proteins. It is minimally metabolized in the liver. Cetirizine is excreted primarily in the urine mainly as unchanged drug. A small amount is excreted in faeces. Cetirizine has an elimination half-life of about 11 hours. The half-life is increased markedly in renal dysfunction. In patients with hepatic dysfunction, the half-life may also be slightly prolonged.

**INDICATIONS**
Adults and children of 3 years or above: For the symptomatic treatment of seasonal and perennial allergic rhinitis, and urticaria of allergic origin.

**SIDE EFFECTS / ADVERSE REACTIONS**
Cetirizine has minimal sedative effects. Any side effects that may occur e.g. agitation, dry mouth, drowsiness or headache, dizziness and sedation, do not differ significantly from placebo. Symptoms of hypersensitivity have been reported occasionally.

**PRECAUTIONS / WARNINGS**
Patients with renal impairment should be given a lower dose because they may have reduced clearance of Cetirizine.

*Pregnancy and lactation:*
Cetirizine is not teratogenic in animals. The safe use of Cetirizine during pregnancy has not been established. As a precaution, Simtec should not be administered to pregnant women during the first three months of pregnancy. It should only be given if the potential benefit justifies the potential risk to the fetus.

*Breast Feeding:* Nursing mothers are advised not to take the drug.

*Activities Requiring Mental Alertness:* In clinical trials the occurrence of somnolence has been reported in some patients taking Cetirizine. Due caution should therefore be exercised when driving a car or operating potentially dangerous machinery.

The safety and effectiveness of cetirizine in pediatric patients under the age of 2 years have not yet been established.

**CONTRAINDICATIONS**
Patients who have shown hypersensitivity to any of the constituents of Simtec. Simtec is also contraindicated during lactation.

**DRUG INTERACTIONS**
There are no reports of hazardous interactions with other drugs to date. Nevertheless, Simtec should be used with caution if sedatives are also being taken. Concomitant administration of Cetirizine with alcohol does not impair psychomotor performance any more than the impairment of performance produced by alcohol alone.

**RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION**
*Adults:* 10mg once daily.

*Children ≥ 6 years:* 10 mg daily, either 5mg twice daily or 10mg once daily.

*Children between 3 and 6 years:* 5mg daily, either 2.5mg twice daily or 5mg once daily.

For patients with renal impairment, dosage should be reduced to 5mg once daily.

For patients with hepatic impairment, a dose of 5mg once a day is recommended.

It is advisable to take the drug with a little liquid during the evening meal since the symptoms for which the product is given usually appear during the night. In patient affected by side effects, the dose may be taken as 5mg in the morning and 5mg in the evening.

**SYMPTOMS AND TREATMENT FOR OVERDOSAGE AND ANTIDOTE(S)**
Drowsiness can be a symptom of overdosage. There is no specific antidote for overdosage. Treatment should be symptomatic and supportive. This may include induction of emesis, gastric lavage to decrease absorption and the use of saline cathartics to enhance elimination.

**PHARMACEUTICAL INFORMATION**
**Storage Conditions**
Store below 30°C in a cool dry place.
Protect from excessive moisture.
Keep out of reach of children.
Jauhi daripada kanak-kanak.

**Shelf life**
Please refer to outer package.

**Pack Size/Package**
Blister packs of 30's, 100's and 500's
Not all pack sizes available locally.

**Route of administration: Oral.**

**Product Registration Holder:**
**DUOPHARMA MARKETING SDN. BHD.**
Lot No. 2, 4, 6, 8 & 10, Jalan P/7, Section 13,
Bangi Industrial Estate,
43650 Bandar Baru Bangi,
Selangor, Malaysia.

**Manufacturer:**
**DUOPHARMA MANUFACTURING (BANGI) SDN. BHD.**
Lot No. 2 & 4, Jalan P/7, Section 13,
Bangi Industrial Estate,
43650 Bandar Baru Bangi,
Selangor, Malaysia.

1500008553 N. 1
Date of revision: May 2019