CETIRIZINE HYDROCHLORIDE

CETRIMAX

℞

10 mg Tablet
Antihistamine (Piperazine derivative)

FORMULATION:
Each tablet contains:
Cetirizine Hydrochloride BP ..... 10 mg

PRODUCT DESCRIPTION:
White, circular, biconvex, film coated, plain tablets.

PHARMACOKINETICS: Cetirizine is rapidly absorbed from the gastrointestinal tract after oral doses, peak plasma concentrations being attained within about an hour. Food delays the time to peak plasma concentrations but does not decrease the amount of drug absorbed. Cetirizine is highly bound to plasma proteins and has an elimination half-life of about 10 hours, it has been detected in breast milk. Cetirizine is excreted primarily in the urine mainly as unchanged drug, it does not appear to cross the blood-brain barrier to a significant extent.

INDICATION: It is used for the symptomatic relief of allergic conditions including rhinitis and chronic urticaria.

DOSAGE AND ADMINISTRATION: In adults and children aged 6 years and over, Cetirizine Hydrochloride is given in an oral dose of 10mg once daily or 5 mg twice daily. Children aged 2 to 5 years may be given Cetirizine 5mg once daily or 2.5 mg twice daily. Or as prescribed by the physician.

DRUG INTERACTIONS: As for the non-sedating antihistamines in general. However, some interactions are less likely with Cetirizine than with non-sedating antihistamines such as astemizole and terfenadine, since Cetirizine appears to have low hepatic metabolism and little arrhythmogenic potential.

PRECAUTIONS: Reduced dosage is recommended for patients with hepatic or renal impairment.

ADVERSE EFFECTS: The more commonly observed untoward events reported during Cetirizine administration and not associated with an equivalent incidence among placebo- treated patients are somnolence, dry mouth and fatigue. The table below shows adverse events occurring with an incidence of greater than 1% after intake of Cetirizine 5 to 20 mg Cetirizine a day. It pools all the American and European clinical studies (including open studies with access to rescue drug) in urticaria, perennial and seasonal rhinitis, the incidence of somnolence associated with was Cetirizine 14.3% (7.6% under placebo) and was predominantly mild to moderate in severity. After pooling the same studies in the three registered indications, sedation is reported more in the patients suffering from seasonal allergic rhinitis, than in the patients suffering from perennial allergic rhinitis and urticaria.

The following events were observed infrequently (less than 2%), in either 3982 adults and children 12 years and older or in 659 paediatric patients aged 6 to 11 years who received Cetirizine in U.S. trials, including an open adult study of six months duration. A causal relationship of these infrequent events with ZYRTEC administration has not been established.

Autonomic Nervous System: anorexia, flushing, increased salivation, urinary retention.

Cardiovascular: cardiac failure, hypertension, palpitation, tachycardia.

Central and Peripheral Nervous Systems: abnormal coordination, ataxia, confusion, dysphonia, hyperesthesia, hyperkinesia, hypertonia, hypoesthesia, leg cramps, migraine, myelitis, paralysis, paresthesia, ptosis, syncope, tremor, twitching, vertigo, visual field defect.

Gastrointestinal: abnormal hepatic function, aggravated tooth caries, constipation, dyspepsa, eructation, flatulence, gastritis, hemorrhoids, increased appetite, melena, rectal hemorrhage, stomatitis including ulcerative stomatitis, tongue discoloration, tongue edema.

Genitourinary: cystitis, dysuria, hematuria, micturition frequency, polyuria, urinary incontinence, urinary tract infection.

Hearing and Vestibular: deafness, earache, ototoxicity, tinnitus.

Metabolic/Nutritional: dehydration, diabetes mellitus, thirst.

Musculoskeletal: arthralgia, arthritis, arthrosis, muscle weakness, myalgia.

Psychiatric: abnormal thinking, agitation, amnesia, anxiety, decreased libido, depersonalization, depression, emotional lability, euphoria, impaired concentration, insomnia, nervousness, paroniria, sleep disorder.

Respiratory System: bronchitis, dyspnea, hyperventilation, increased sputum, pneumonia, respiratory disorder, rhinitis, sinusitis, upper respiratory tract infection.

Reproductive: dysmenorrhea, female breast pain, intermenstrual bleeding, leukorrhea, menorrhagia, vaginitis.

Reticuloendothelial: lymphadenopathy.

Skin: acne, alopecia, angioedema, bullous eruption, dermatitis, dry skin, eczema, erythematous rash, furunculosis, hyperkeratosis, hypertrichosis, increased sweating, maculopapular rash, photosensitivity reaction, photosensitivity toxic reaction, pruritus, purpura, rash, seborrhea, skin disorder, skin nodule, urticaria.

Special Senses: parosmia, taste loss, taste perversion.

Vision: blindness, conjunctivitis, eye pain, glaucoma, loss of accommodation, ocular hemorrhage, xerophthalmia.

Body as a Whole: accidental injury, asthenia, back pain, chest pain, enlarged abdomen, face edema, fever, generalized edema, hot flashes, increased weight, leg edema, malaise, nasal polyp, pain, pallor, periorbital edema, peripheral edema, rigors.

Occasional instances of transient, reversible hepatic transaminase elevations have occurred during Cetirizine therapy. Hepatitis with significant transaminase elevation and elevated bilirubin in association with the use of Cetirizine has been reported.

In foreign marketing experience the following additional rare, but potentially severe adverse events have been reported: anaphylaxis, cholestasis, glomerulonephritis, hemolytic anemia, hepatitis, orofacial dyskinesia, severe hypotension, stillbirth, and thrombocytopenia.

REPORTING OF SUSPECTED ADVERSE REACTIONS: To allow continued monitoring of benefit/risk balance of the medicinal product, reporting of adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA: www.fda.gov.ph. Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

	Number of Patients (%)	
Adverse Experience by WHO grouping	Cetrizine(n=2,487)	Placebo(n=1,577)
Somnolence	356 (14.3%)	120 (7.6%)
Headache	272 (10.2%)	177 (11.2%)
Dry Mouth	122 (5.0%)	29 (1.8%)
Fatigue	85 (3.4%)	26 (1.6%)
Nausea	51 (2.1%)	48 (3.0%)
Dizziness	49 (2.0%)	26 (1.6%)
Pharyngitis	34 (1.4%)	15 (1.8%)
Insomnia	29 (1.2%)	17 (1.1%)
Dyspepsia	21 (0.8%)	23 (1.5%)
Pruritus	5 (0.2%)	16 (1.0%)

Assessment of severity of sedation in clinical trials indicates the mild nature of sedation associated with Cetirizine. The following events were observed infrequently (less than 11100), but more than once, in 2,487 patients who received Cetirizine in all US and European trials, a causal relationship with Cetirizine administration has not been established. Events are listed in order of decreasing frequency within a given body system.

Autonomic nervous system: Increased appetite, anorexia, flushing, increased sweating. **Cardiovascular:** Palpitations/tachycardia. **ENT:** Earache, epistaxis, altered sense of taste, tinnitus, tonguedisorder. **Vision:** Eye abnormality, periorbital oedema, abnormalvision, eye pain, conjunctivitis. **Gastrointestinal:** Abdominal pain, diarrhea, vomiting, constipation, flatulence. **Genitourinary:** Polyuria, urinary retention, urinary tract infection. **Musculoskeletal:** Back pain, myalgia, arthralgia, bone disorder (fracture), leg cramps. Neurologic. Nervousness, impaired concentration, confusion, paraesthesia, asthenia, hypertonia, tremor. **Respiratory System:** Respiratory disorder, coughing, bronchospasm, upper respiratory tract infection, dyspnoea. **Miscellaneous:** Weight increase (see comment below), fever, edema, chest pain, rigors, dysmenorrhea, thirst, decreased libido, Weight gain was reported as an adverse effect in 0.4% of Cetirizine patients in placebo-controlled trials. In an open study of sill months' duration, the mean gain in weight was 2.8% after 20 weeks, with no further increase at 26 weeks. This effect has been reported for other antihistamines.

Occasional instances of reversible liver function test (tränsaminase) elevations have occurred during cetirizine therapy, without evidenceof jaundice, hepatitis or other clinical findings.

PRECAUTIONS: Reduced dosage is recommended for patients with hepatic or renal impairment.

CAUTION: Foods, Drugs, Devices and Cosmetics Act prohibits dispensingwithout prescription.

STORAGE CONDITION: Store at temperatures not exceeding 30°C.

AVAILABILITY: Alu-Alu Blister Pack x 10's Box of 100's

FDA Registration Number: DR-XY41282

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