CETRIZ SYRUP.
(CETIRIZINE ORAL SOLUTION.)

MODULE 1	ADMINISTRATIVE INFORMATION AND PRESCRIBING INFORMATION

1.4 product information
1.4.1 Prescribing information (Summary of product characteristics)
1. Name of the medicinal product
Cetriz Syrup.

2. Qualitative and quantitative composition
Each 5mL Contains: Cetirizine HCl BP 5mg.
For full list of Excipients, see section 6.1.

3.Pharmaceutical form
Syrup for oral administration.
Light green clear viscous liquid packed in 60mL Amber PET bottle in a unit box along with literature insert.

4. Clinical particulars
4.1 Therapeutic indications.
Cetriz® is indicated for the relief of symptoms associated with both seasonal and perennial allergic rhinitis.
It effectively treats the symptoms associated with these two conditions which are sneezing, rhinorrhea, nasal pruritus, ocular pruritus, redness of the eyes: tearing and post nasal discharge.
Cetriz® is also indicated for the treatment of uncomplicated skin manifestations of chronic idiopathic urticaria as it significantly reduces the occurrence, severity and duration of hives and pruritus.

4.2 Posology and method of administration
Cetriz® is administered orally as a single daily dose, with or without food and at varying times convenient to the patient as follows; Adults and children 6 years and older;5mg or 10mg initially depending on the severity of the symptoms:
Children 2 to 5 years; 2.5mg initially once daily.
The dosage may be increased to 5mg given either as a single daily dose or 2.5mg in two doses per day depending on the severity of the symptoms or on the patient's response.

4.3 Contraindications
The administration of Cetriz® is contraindicated in those patients known to be hypersensitive to Cetirizine or hydroxyzine or to any of the ingredients of Cetriz®.

4.4 Special warnings and precautions for use.
Though **Cetriz® lacks** significant sedative effects, somnolence has been observed in a few patients.
Patients on Cetriz® medication should therefore be cautioned to exercise due care when driving or operating machinery.
Concurrent use of alcohol or other CNS depressants should be avoided as they will further reduce mental alertness and additionally impair CNS performance.
Cetriz® should be used in pregnancy only if clearly needed as there are no adequate and well controlled studies to verify its safety in pregnancy.
The use of **Cetriz®** in nursing mothers is not recommended as Cetirizine is excreted in human breast milk and its safety in children below 2 years is yet to be established.

4.5 Interaction with other medicinal products and other forms of interaction
Due to the pharmacokinetic, pharmacodynamic and tolerance profile of cetirizine, no interactions are expected with this antihistamine. Actually, neither pharmacodynamic nor significant pharmacokinetic interaction was reported in drug-drug interactions studies performed, notably with pseudoephedrine or theophylline (400 mg/day). At therapeutic doses, no clinically significant interactions have been demonstrated with alcohol (for a blood alcohol level of 0.5 g/l. Nevertheless, precaution is recommended if alcohol is taken concomitantly. The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased.

In sensitive patients, the concurrent use of alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance although cetirizine does not potentiate the effect of alcohol (0.5 g/l blood levels).
Concomitant use of cetirizine with other CNS depressants should be avoided as reduction in alertness and impairment of performance may occur.

4.6 Pregnancy and lactation
Pregnancy
For cetirizine, very rare clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant women.
Breast-feeding
Cetirizine is excreted in human milk at concentrations representing 25% to 90% of those measured in plasma, depending on sampling time after administration. Caution therefore should be exercised when prescribing cetirizine to lactating women.
Fertility
Limited data is available on human fertility but no safety concern has been identified. Animal data show no safety concern for human reproduction.

4.7 Effects on ability to drive and use machines
Objective measurements of driving ability, sleep latency and assembly line performance have not demonstrated any clinically relevant effects at the recommended dose of 10 mg.
Patients intending to drive, engage in potentially hazardous activities or operate machinery should not exceed the recommended dose and should take their response to the medicinal product into account.
In sensitive patients, concurrent use with alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance.

4.1 Undesirable effect
Most adverse reactions with therapy involving **Cetriz®** are mild or moderate. Although **Cetriz®** has insignificant sedative effect in most patients, the most common adverse reaction with an incidence of about 6% is somnolence and is dose related in such persons. Other common adverse reactions are fatigue, dry mouth, dizziness and pharyngitis, headache and nausea. In children some other adverse reactions that have been observed include abdominal pain, diarrhoea, vomiting, coughing, bronchospasm and epistaxis.

4.9 Overdose and treatment
The most significant clinical sign observed in overdosing in adults is somnolence. In children increased irritability and restlessness occurs initially followed by drowsiness. In case of overdosage symptomatic or supportive therapy should be instituted as Cetriz® has no known specific antidote and is neither effectively removed by dialysis.

5. Pharmacological properties
5.1 Pharmacodynamic properties
Pharmacotherapeutic classification: **PIPERAZINE DERIVATIVES**.
ATC CODE: R06AE07 (ATC classification system)
Cetirizine is an anti-allergic agent that is a human metabolite of hydroxyzine. It exerts its antihistaminic activity through selective inhibition of peripheral H, receptors. Cetirizine has negligible anticholinergic and ant-serotonergic activity. Cetirizine shows negligible penetration into the brain and as such exhibit's low potential for drowsiness for normal therapeutic doses. Cetirizine is rapidly absorbed following oral administration, the time to achieve peak plasma concentration with 10mg being approximately 1 hour.
A peak to plasma concentration of 311ng/ml is eventually attained following multiple 10mg dally oral dosage and no accumulation occurs.

Presence of food in the gastrointestinal tract only delays the absorption of Cetirizine following oral administration but the blood profile remains unaffected Skin wheal and flare formation caused by intradermal injection of histamine in most subjects is inhibited within 20 minutes to 1hour and persists for at least 24 hours following oral administration of 5mg to 20mg of Cetirizine.
Prolonged administration of 10mg dally dose for a period of 35 days has failed to demonstrate development of tolerance to the anti-histaminic effects of Cetirizine.
Allergic reactions caused by histamine and other mediators or histamine releasers when induced by intradermal injection of these agents are inhibited by the administration of Cetirizine.
Cetirizine also inhibits the response to a cold challenge in patients with cold-induced Urticaria.
Cetirizine blocks bronchoconstriction induced by inhalation of nebulized histamine in patients with mild asthma. 93% of Cetirizine is bound to plasma proteins with plasma concentrations of 25 to 1000 ng/ml.
The elimination half-life in healthy subjects is 8.3 hours with an apparent total clearance of about 53 ml per minute. In the elderly, the elimination half-life Increases and may be related to decreased renal function.
Cetirizine is metabolized in the liver by O-dealkylation to a metabolite with insignificant antihistaminic activity. About 70% of an administered dose is excreted in urine and 10% in faeces. 50% of the drug excreted in urine is in the unchanged form.
Slight interaction with theophylline 400mg daily and 20mg Cetirizine daily results in reduction of Cetirizine clearance by about 16%. Half-life of Cetirizine increases 3-fold and its urine clearance decreases by 70% in patients with moderately impaired renal function and having creatinine clearance of between 11 - 31ml per minute. Similar events are observed 10 cases of liver malfunction.

5.2 Pharmacokinetic properties
Cetirizine is rapidly absorbed from the gastrointestinal tract; absorption is not reduced by food, though the rate may be decreased slightly. Peak blood levels in the order of 0.3 micrograms/ml are attained between 30- and 60-minutes following administration of a 10 mg oral dose of cetirizine. Apparent plasma clearance is greater in children than in adults: the terminal elimination half-life in healthy adult volunteers ranges between 6.7 – 10.7 hours; in children 6.1 – 7.1 hours; and in children aged under 4 years 5.55 hours. Cetirizine is mainly excreted unchanged in the urine (approximately 70% over 5 days compared with 10% in the faeces). The half-life is increased in renal dysfunction: half-lives of 19 and 21 hours in patients with mild to moderate renal impairment respectively have been reported. This may have implications for elderly patients. Cetirizine binds strongly to plasma proteins.

5.3 Preclinical data safety
No relevant information additional to that contained elsewhere in the SPC.

6. Pharmaceutical particulars
6.1 List of excipients
Sodium Carboxymethyl Cellulose (Blanose)
Sodium Benzoate
Sodium Saccharin
Brilliant Blue Soluble Colour
Raspberry Essence liquid
Purified water.

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 Months from the date of manufacture.

6.4 Special precautions for storage
Store in a dry place below 30°C.

Protect form light.
Keep all medicines out of reach of children.
Replace cap securely after use.

6.5 Nature and contents of container
Light green clear viscous liquid packed in 60mL Amber PET bottle in a unit box along with literature insert.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses Marketing Authorization Holder:
Company Name: LABORATORY & ALLIED LTD
Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa Road,
P.O. Box 42875 GPO 00100, Nairobi,
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E-Mail: info@laballied.com.

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9. Date of first Registration/ Renewal of the Registration:
Marketing Authorization Number: H2008/18298/528.
First registration date: 7th/04/2009.
Renewal: Retained annually.

10. Date of revision of the text:
March 2024.