MEDIZINE SYRUP 5mg/5ml

Each 5ml contains :
Cetirizine HCl 5mg

Pharmacology:
In experimental animals, cetirizine has been shown to be an anti-H1 agent devoid of any significant anticholinergic or antiserotonin effects. At pharmacological active doses, it induces neither sedation nor behavioural changes. This may be explained by the fact that cetirizine does not cross the blood-brain barrier. It was shown in human pharmacology studies that cetirizine will inhibit certain effects produced by exogenous histamine. This activity appears rapidly. Cetirizine also inhibits the effects produced by endogenous histamine released in vivo by an agent eg 48/80. Finally, it inhibits the cutaneous reaction induced by VIP (Vasoactive Intestinal Polypeptide) and substance P, neuropeptides that are believed to take part in the allergic reaction. Cetirizine markedly reduces bronchial hyper-reactivity to histamine in the asthmatic patient. It also reduces the allergic reaction induced by specific allergens. These effects are obtained without central effects being demonstrated either by psychometric test or by a quantified EEG.

Pharmacokinetics:
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.

Indications:
Adults and children of 2 years and above: symptomatic treatment of seasonal allergic rhinitis, perennial allergic rhinitis and urticaria of allergic origin.

Side Effects / Adverse Reactions:

Blood and lymphatic disorders	Very rare: thrombocytopenia
Immune system disorders	Rare: hypersensitivity Very rare: anaphylactic shock
Metabolism and nutrition disorders	Not known: increased appetite
Psychiatric disorders	Uncommon: agitation Rare: aggression, confusion, depression, hallucination, insomnia Very rare: tics Not known: suicidal ideation, nightmare
Nervous system disorders	Uncommon: paraesthesia Rare: convulsions Very rare: dysgeusia, dyskinesia, dystonia, syncope, tremor Not known: amnesia, memory impairment
Eye disorders	Very rare: accommodation disorder, blurred vision, oculogyration
Ear and labyrinth disorders	Not known: vertigo
Cardiac disorders	Rare: tachycardia
Gastrointestinal disorders	Uncommon: diarrhoea
Hepatobiliary disorders	Rare: hepatic function abnormal (transaminases increased, blood bilirubin increased, blood alkaline phosphatase increased, gamma-glutamyl transferase increased) Not known: hepatitis
Skin and subcutaneous tissue disorders	Uncommon: pruritus, rash Rare: urticaria Very rare: angioedema, fixed drug eruption Not known: acute generalized exanthematous pustulosis (AGEP)
Musculoskeletal and connective tissue disorders	Not known: arthralgia
Renal and urinary disorders	Very rare: dysuria, enuresis Not known: urinary retention (see Section Warnings and Precautions)
General disorders and administration site conditions	Uncommon: asthenia, malaise Rare: oedema
Investigations	Rare: weight increased

Skin reactions occuring after discontinuation of cetirizine
After discontinuation of cetirizine, pruritus (intense itching) and/or urticaria have been reported (see Section Warnings and Precautions).

Precautions/Warnings:

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.
Dosage adjustment is necessary in patients with moderate or severe renal impairment (see section Recommended Dose). Caution should be taken in patients with predisposition factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as cetirizine may increase the risk of urinary retention.Caution in epileptic patients and patients at risk of convulsions is recommended. For patients whose symptoms persist, it is advised to consult a doctor or pharmacist. At therapeutic doses, no clinically signification 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. Allergy skin tests are inhibited by antihistamines and a wash-out period (of 3 days) is required before performing them. Pruritus and/or urticaria may occur when cetirizine is stopped, even if those symptoms were not present before treatment initiation. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted. Paediatric population: Due to the amount of some excipients in the formulation, the use of the product is not recommended in children aged less than 2 years.

Use in pregnancy & lactation:

Fertility: Limited data is available on human fertility but no safety concern has been identified.
Animal data show no safety concern for human reproduction.
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.

Contraindications:

Cetirizine is contraindicated in:
hypersensitivity to any of the constituents of this formulation, to hydroxyzine or to any piperazine derivatives.
patients with severe renal impairment at less than 10 ml/min creatinine clearance.

Dosage:

Route of Administration: For oral use.

Adults: 10 mg (10 ml oral solution) once daily. A 5 mg starting dose (5 ml of oral solution) may be proposed if this leads to satisfactory control of the symptoms.

Children:
Children aged from 2 to 6 years: 2.5 mg (2.5 ml of oral solution bid) twice daily.
Children aged from 6 to 12 years: 5 mg (5 ml of oral solution) twice daily.
Children over 12 years of age: 10 mg (10 ml of oral solution) once daily.

Elderly: Data do not suggest that the dose needs to be reduced in elderly subjects provided that the renal function is normal.

Patients with moderate to severe renal impairment:
Since cetirizine is mainly excreted via renal route, in cases no alternative treatment can be used, the dosing intervals must be individualised according to renal function. Refer to the following table and adjust the dose as indicated. To use this dosing table, an estimate of the patient's creatinine clearance (CLcr) in ml/min is needed. The CLcr (ml/min) may be estimated from serum creatinine (mg/dl) determination using the following formula:

CLcr= [140-age(years]) x weight (kg)/[72 x serum creatinine (mg/dl)] (x 0.85 for women)

Dosing adjustments for adult patients with impaired renal function

Group	Creatinine clearance (ml/min)	Posology and frequency
Normal	≥80	10 mg once daily
Mild	50-79	10 mg once daily
Moderate	30-49	5 mg once daily
Severe	< 30	5 mg once every 2 days
End-stage renal disease – Patients undergoing dialysis	< 10	contraindicated

In paediatric patients suffering from renal impairment, the dose will have to be adjusted on an individual basis taking into account the renal clearance, age and body weight of the patient.

Patients with hepatic impairment
No dose adjustment is needed in patients with solely hepatic impairment.
Patients with hepatic impairment and renal impairment:
Dose adjustment is recommended (see Patients with renal impairment above)

Drug Interactions:

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).
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).

Symptoms and Treatment for overdosage and antidote(s):

Symptoms observed after an overdose of cetirizine are mainly associated with CNS effects or with effects that could suggest an anticholinergic effect.
Adverse events reported after an intake of at least 5 times the recommended daily dose are: confusion, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, restlessness, sedation, somnolence, stupor, tachycardia, tremor and urinary retention.
There is no known specific antidote to cetirizine. Should overdose occur, symptomatic or supportive treatment is recommended.
Gastric lavage should be considered following ingestion of a short occurrence. In addition active charcoal should be considered if cetirizine has been ingested within 1 hour.
Cetirizine is not effectively removed by dialysis.

Effects on Ability to Drive and Use Machine:

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. However, patients who experience somnolence should refrain from driving, engaging in potentially hazardous activities or operating machinery. They 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.

Marketed in Malaysia:

Pack size: PET, amber bottle pack of 120ml.

Storage conditions: Store at or below 30ºC. Protect from light.

Shelf-life: 2 years.

Description: Syrup : A clear, colourless syrup with banana flavour.

FURTHER INFORMATION CONCERNING THIS DRUG CAN BE OBTAINED FROM YOUR FAMILY PHYSICIAN / LOCAL GENERAL PRACTITIONER / PHARMACIST.

Manufacturer:
SUNWARD PHARMACEUTICAL SDN. BHD.
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Revised Date : 11/09/2025