

SUMMARY OF PRODUCT CHARACTERISTICS
ATRIZEX Syrup (Cetirizine Hydrochloride 5 mg/5 ml Oral Solution)

1. NAME OF THE MEDICINAL PRODUCT

ATRIZEX Syrup (Cetirizine Hydrochloride 5 mg/5 ml Oral Solution)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of oral solution contains 5 mg cetirizine hydrochloride.

Excipients with known effect:

Each 5 ml contains 50 mg sorbitol.

Each 5 ml contains 0.2 mg methylparaben sodium.

Each 5 ml contains 0.5 mg propylparaben sodium.

This medicinal product contains less than 1 mmol sodium per dose (5 ml), that is to say essentially 'sodium-free'.

For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.

Clear, light-yellow syrup.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Cetirizine hydrochloride oral solution is indicated in adults and children aged 2 years and above:

- For the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- For the relief of symptoms of chronic idiopathic urticaria.

4.2 Posology and method of administration

Adults and adolescents over 12 years

10 mg once daily (10 ml oral solution).

Children aged 6 to 12 years

5 mg twice daily (5 ml oral solution twice daily).

Children aged 2 to 6 years

2.5 mg twice daily (2.5 ml oral solution twice daily).

Renal impairment

Group	eGFR (ml/min)	Dose and frequency
Normal renal function	≥90	10 mg once daily
Mildly decreased	60–<90	10 mg once daily
Moderately decreased	30–<60	5 mg once daily
Severely decreased	15–<30 (not requiring dialysis)	5 mg once every 2 days
End-stage renal disease	<15 (requiring dialysis)	Contraindicated

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

Hepatic impairment

No dose adjustment is needed in patients with solely hepatic impairment. In patients with hepatic impairment and concomitant renal impairment, adjustment of the dose is recommended as above.

Elderly

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

Method of administration

Oral. The solution can be swallowed as such. Calibrated measuring spoon should be used.

4.3 Contraindications

- Hypersensitivity to cetirizine, to any of the excipients listed in section 6.1, to hydroxyzine or to any piperazine derivatives.
- Patients with end-stage renal disease with an eGFR below 15 ml/min.

4.4 Special warnings and precautions for use

At therapeutic doses, no clinically significant interactions have been demonstrated with alcohol (blood alcohol level of 0.5 g/l). Nevertheless, precaution is recommended if alcohol is taken concomitantly.

Caution should be taken in patients with predisposing factors for urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as cetirizine may increase the risk of urinary retention.

Caution is recommended in epileptic patients and patients at risk of convulsions.

Response to allergy skin tests is 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.

Sorbitol content

This medicinal product contains 50 mg sorbitol per 5 ml dose. Patients with hereditary fructose intolerance (HFI) should not take this medicinal product. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Paraben content

This medicinal product contains methylparaben sodium and propylparaben sodium, which may cause allergic reactions (possibly delayed).

Paediatric population

Due to the amounts of some excipients in the formulation, the use of this product is not recommended in children aged less than 2 years.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant pharmacodynamic or pharmacokinetic interactions have been demonstrated with this antihistamine at therapeutic doses. No significant interactions were reported 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, 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 at 0.5 g/l blood levels.

4.6 Fertility, pregnancy and lactation

Pregnancy

For cetirizine, prospectively collected data on pregnancy outcomes do not suggest potential for maternal or foetal/embryonic toxicity above background rates. Animal studies do not indicate direct or indirect harmful effects. Caution should nevertheless be exercised when prescribing to pregnant women.

Breast-feeding

Cetirizine is excreted in human milk at concentrations representing 25–90% of those measured in plasma, depending on sampling time after administration. Caution should be exercised when prescribing cetirizine to lactating women, as a risk of side effects in breastfed infants cannot be excluded.

Fertility

Limited data are 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. However, patients who experience somnolence should refrain from driving or engaging in potentially hazardous activities. They should not exceed the recommended dose and should take their response to the product into account.

4.8 Undesirable effects

Summary of the safety profile

Cetirizine at the recommended dosage has minor undesirable effects on the CNS, including somnolence, fatigue, dizziness and headache. In some cases, paradoxical CNS stimulation has been reported. Isolated cases of abnormal hepatic function with elevated hepatic enzymes accompanied by elevated bilirubin have been reported; these mostly resolve upon discontinuation.

Adults and adolescents — tabulated summary

Frequencies from placebo-controlled clinical trials (n=3,260 cetirizine-treated patients):

System Organ Class	Adverse Reaction	Cetirizine 10 mg	Placebo
Nervous system disorders	Dizziness	1.10%	0.98%
	Headache	7.42%	8.07%
Psychiatric disorders	Somnolence	9.63%	5.00%
Gastrointestinal disorders	Abdominal pain	0.98%	1.08%
	Dry mouth	2.09%	0.82%
	Nausea	1.07%	1.14%
General disorders	Fatigue	1.63%	0.95%
Respiratory disorders	Pharyngitis	1.29%	1.34%

Paediatric population (6 months to 12 years)

Adverse reactions at rates of 1% or greater in children in placebo-controlled trials:

System Organ Class	Adverse Reaction	Cetirizine (n=1,656)	Placebo (n=1,294)
Gastrointestinal disorders	Diarrhoea	1.0%	0.6%
Psychiatric disorders	Somnolence	1.8%	1.4%
Respiratory disorders	Rhinitis	1.4%	1.1%
General disorders	Fatigue	1.0%	0.3%

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

Symptoms

Symptoms are mainly associated with CNS effects or anticholinergic effects. Adverse events reported after an intake of at least 5 times the recommended daily dose include: confusion, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, restlessness, sedation, somnolence, stupor, tachycardia, tremor, and urinary retention.

Management

There is no known specific antidote. Symptomatic or supportive treatment is recommended. Gastric lavage may be considered shortly after ingestion. Cetirizine is not effectively removed by haemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines for systemic use, piperazine derivatives. ATC code: R06AE07.

Cetirizine, a human metabolite of hydroxyzine, is a potent and selective antagonist of peripheral H₁-receptors. In vitro receptor binding studies have shown no measurable affinity for receptors other than H₁. At a dose of 10 mg once or twice daily, it inhibits the late phase recruitment of eosinophils in the skin and conjunctiva of atopic subjects submitted to allergen challenge. Cetirizine strongly inhibits wheal and flare reactions induced by high concentrations of histamine in skin. In a placebo-controlled study, cetirizine given at 60 mg/day for 7 days did not cause statistically significant QT prolongation.

5.2 Pharmacokinetic properties

Absorption

Steady-state peak plasma concentration is approximately 300 ng/ml and is achieved within 1.0 ± 0.5 hours. The extent of bioavailability is similar when cetirizine is given as solutions, capsules or tablets. Absorption is not reduced with food, although the rate is decreased.

Distribution

Apparent volume of distribution 0.50 l/kg. Plasma protein binding $93 \pm 0.3\%$. Cetirizine does not modify the protein binding of warfarin.

Biotransformation

Cetirizine does not undergo extensive first-pass metabolism.

Elimination

Terminal half-life approximately 10 hours. No accumulation observed with daily doses of 10 mg for 10 days. Approximately two-thirds of the dose are excreted unchanged in urine. Cetirizine exhibits linear kinetics over the range of 5–60 mg.

Special populations

Renal impairment: Patients with moderate renal impairment had a 3-fold increase in half-life and 70% decrease in clearance vs healthy volunteers. Dose adjustment is necessary in moderate or severe renal impairment (see section 4.2).

Hepatic impairment: Patients with chronic liver diseases had a 50% increase in half-life and 40% decrease in clearance. Dose adjustment is only necessary if concomitant renal impairment is present.

Elderly: Half-life increased by approximately 50% and clearance decreased by 40%, related to decreased renal function.

Paediatric population: Half-life approximately 6 hours in children 6–12 years; approximately 5 hours in children 2–6 years; approximately 3.1 hours in infants and toddlers 6–24 months.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol solution (excipient with known effect), glycerin, saccharin sodium, hydroxyethyl cellulose, methylparaben sodium (excipient with known effect), propylparaben sodium (excipient with known effect), citric acid, sucrose, pineapple flavour, sunset yellow, purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Finished product: 3 years. After first opening: 3 months. Discard any remaining solution 3 months after first opening.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions. Keep out of the reach and sight of children.

6.5 Nature and contents of container

60 ml in amber-coloured glass or PET bottle. Pack size: 60 ml.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

DANNES PHARMACY LTD

P.O. Box 774-00521, Nairobi, Kenya.

Manufacturer: STEDAM PHARMA MANUFACTURING LTD

North Airport Road, Plot No LR.20753, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2025/CTD111110/15348

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

26.11.2025

10. DATE OF REVISION OF THE TEXT

26.11.2025