SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

Cetrizet D, Cetirizine Hydrochloride 5 mg and Pseudoephedrine Hydrochloride 120 mg Extended Release Tablets.

2. Qualitative and quantitative composition

Each film-coated tablet contains:

Active substance	Quantity per tablet
Cetirizine Hydrochloride BP	5 mg
Pseudoephedrine Hydrochloride BP	120 mg

Excipient of known effect: lactose monohydrate. For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Film-coated tablet.

4. Clinical particulars

4.1 Therapeutic indications

Cetrizet D is indicated for the treatment of symptoms such as nasal congestion, sneezing, rhinorrhoea and nasal and ocular pruritus associated with seasonal or perennial allergic rhinitis. Cetrizet D should be administered when the anti-allergic properties of cetirizine hydrochloride and the nasal decongestant activity of pseudoephedrine hydrochloride are desired.

4.2 Posology and method of administration

Adults: One tablet two times a day, morning and evening, corresponding to the maximum recommended dose of 10 mg cetirizine and 240 mg pseudoephedrine daily.

Paediatric population: Adolescents from 12 years of age and above: one tablet two times a day, morning and evening, with or without food. Children under 12 years of age: use is contraindicated.

Renal impairment: The dosage intervals must be individualized according to renal function as follows:

Group	Creatinine clearance (mL/min)	Dosage and frequency
Normal renal function	> 90	1 tablet twice daily
Mildly decreased renal function	60 - < 90	1 tablet twice daily
Moderately decreased renal function	30 - < 60	1 tablet once daily
Severely decreased renal function	15 - < 30 not requiring dialysis	1 tablet once every 2 days
End-stage renal disease	< 15 requiring dialysis treatment	Contraindicated

Hepatic impairment: The dose should be reduced to one tablet daily in patients with moderate hepatic insufficiency.

Duration of treatment: The duration of treatment should not exceed the period of symptoms and should not exceed two to three weeks at the recommended dose of one tablet twice daily. After disappearance of nasal symptoms, treatment should be continued with an antihistamine alone.

Method of administration: Tablets should be swallowed whole with some liquid and must not be broken, chewed or crushed. The tablets may be taken with or without food.

4.3 Contraindications

Cetrizet D is contraindicated in patients with:

- known hypersensitivity to cetirizine, pseudoephedrine or to any of the excipients listed in section 6.1;
- hypersensitivity to piperazine;
- hypertension or ischaemic heart disease;
- end-stage renal disease, including patients with creatinine clearance less than 15 mL/min;
- uncontrolled hyperthyroidism;
- severe arrhythmias;
- phaeochromocytoma;
- elevated intraocular pressure;
- urinary retention;
- during administration of antihypertensives such as beta-blockers, sympathomimetics, dihydroergotamine or amphetamines;
- during treatment with monoamine oxidase inhibitors (MAOIs) or up to two weeks after discontinuation of MAOIs;
- history of stroke or increased risk of haemorrhagic stroke. This includes concomitant treatment with vasoconstrictors such as bromocriptine, pergolide, lisuride, cabergoline, ergotamine or dihydroergotamine, or any other decongestant used by oral or nasal route, as vasoconstriction and elevated blood pressure increase the risk of haemorrhagic stroke.
- children under 12 years of age.

4.4 Special warnings and precautions for use

The physician or pharmacist should reassure himself that sympathomimetic-containing preparations are not simultaneously administered by several routes, for example orally and topically, including nasal, aural and eye preparations.

Cetirizine-pseudoephedrine should be used with caution in patients over 50 years of age; patients with diabetes mellitus, hyperthyroidism, tachycardia, cardiac arrhythmia, moderate hepatic or renal insufficiency; and in cases of ingestion of alcohol or other central nervous system depressants.

Caution is required in patients with conditions where anticholinergic activity is undesirable, including patients with predisposing factors for urinary retention such as spinal cord lesion or prostatic hyperplasia, and in patients with hypertension treated with non-steroidal anti-inflammatory drugs.

Cetrizet D is contraindicated in children under 12 years of age because the combination has not been appropriately studied in this age group and because of the presence of pseudoephedrine.

Caution should be exercised in patients at risk of hypercoagulability, for example inflammatory bowel disease, due to the vasoconstrictor effect of pseudoephedrine. The product should be discontinued and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported with pseudoephedrine-containing products. Pseudoephedrine should be discontinued and medical advice sought immediately if sudden severe headache, nausea, vomiting, confusion, seizures or visual disturbances occur.

Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.

Caution is required where patients are taking sympathomimetics, decongestants, anorexigenic substances, psychostimulants, tricyclic antidepressants, linezolid, guanethidine, reserpine, phenothiazines, antihypertensives or non-steroidal anti-inflammatory drugs. It is also required in hypertensive patients treated concomitantly with NSAIDs.

The product may act as a cerebral stimulant, giving rise to insomnia, nervousness, hyperpyrexia, tremor and epileptiform convulsions. Cases of abuse have been reported with pseudoephedrine.

At therapeutic doses, no clinically significant interaction of cetirizine has been reported with alcohol, but caution is recommended with alcohol or other CNS depressants.

Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. Patients should be carefully monitored and treatment discontinued if signs and symptoms such as pyrexia, erythema or small pustules are observed.

Athletes should be informed that treatment with pseudoephedrine can lead to positive results in doping tests. Allergy skin tests are inhibited by antihistamines and an appropriate wash-out period of three days is required before performing them.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. This medicine contains less than 1 mmol sodium (23 mg) per dose and is considered sodium-free.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been reported with the combination medicinal product cetirizine-pseudoephedrine. No clinically significant interaction has been reported with cetirizine, but caution is recommended on concomitant use of sedatives.

In a multiple dose study of theophylline 400 mg once daily and cetirizine 10 mg daily, a small decrease in cetirizine clearance was noted, while theophylline disposition was not altered. In a study with ritonavir 600 mg twice daily and cetirizine 10 mg daily, cetirizine exposure increased and ritonavir disposition was slightly altered.

Concomitant use of cetirizine-pseudoephedrine with MAOIs or beta-blockers can cause blood pressure to increase. Due to the long duration of MAOI action, the interaction remains possible for two weeks after discontinuation of treatment. An increase in blood pressure can also occur with concomitant dihydroergotamine or linezolid.

The following combinations are not recommended because of risk of vasoconstriction and increased blood pressure: bromocriptine, cabergoline, lisuride, pergolide, as well as dihydroergotamine, ergotamine, methylergometrine and other vasoconstrictors used orally or nasally as decongestants.

Sympathomimetic amines can reduce the antihypertensive effect of drugs which interfere with sympathetic activity, including methyldopa and alpha- and beta-adrenergic blocking agents. Tricyclic antidepressants can potentiate the hypertensive effect of pseudoephedrine.

The ectopic activity of a pacemaker can be increased when pseudoephedrine is used with cardiac glycosides such as digoxin or digitoxin; use is not advised in patients treated with cardiac glycosides. Antacids and proton pump inhibitors increase pseudoephedrine absorption, while kaolin reduces absorption.

Concurrent use with halogenated anaesthetic agents such as chloroform, enflurane, isoflurane, cyclopropane or halothane may provoke or worsen ventricular arrhythmia. Concurrent alcohol or other CNS depressants may further reduce alertness and impair performance, although no negative effects of pseudoephedrine have been reported nor are they expected.

4.6 Fertility, pregnancy and lactation

Pregnancy: There are no or limited data from use of cetirizine-pseudoephedrine in pregnant women. Cetirizine-pseudoephedrine is not recommended during pregnancy. Pseudoephedrine use during the first trimester has been associated with an increased frequency of gastroschisis and small intestinal atresia. Due to the vasoconstrictive properties of pseudoephedrine, cetirizine-pseudoephedrine should not be used during the third trimester as it can induce a reduction in uteroplacental circulation. Animal reproductive toxicity data for cetirizine are insufficient.

Breast-feeding: Cetirizine and pseudoephedrine are excreted in human milk. Cetrizet D is not recommended during breast-feeding.

Fertility: A reported study in rats did not reveal an impact on fertility at an oral dose of 160 mg/kg cetirizine and 153.6 mg/kg pseudoephedrine; the relevance of this to human fertility is unknown.

4.7 Effects on ability to drive and use machines

Patients intending to drive, perform potentially hazardous activities or operate machinery should not exceed the recommended dose and should consider their response to the medicinal product. Patients who experience somnolence should refrain from driving, engaging in potentially hazardous activities or operating machinery.

Objective measurements of driving ability, sleep latency and assembly line performance have not demonstrated clinically relevant effects with cetirizine at the approved dose of 10 mg daily. No negative effects of pseudoephedrine on the ability to drive and use machines have been reported or are expected; however, variations in response may occur and some patients may experience central nervous system effects.

4.8 Undesirable effects

The following table lists undesirable effects by system organ class and frequency. Frequencies are defined as very common (>=1/10), common (>=1/100 to <1/10), uncommon (>=1/1,000 to <1/100), rare (>=1/10,000 to <1/1,000), very rare (<1/10,000), and not known (cannot be estimated from available data).

System organ class	**Frequency**	**Adverse reactions**
Immune system disorders	Rare	Hypersensitivity reactions including anaphylactic shock
Psychiatric disorders	Common	Nervousness, insomnia
Psychiatric disorders	Uncommon	Agitation, anxiety
Psychiatric disorders	Rare	Hallucinations
Psychiatric disorders	Very rare	Psychotic disorder
Psychiatric disorders	Not known	Aggression, confusional state, depression, tic, euphoric mood, suicidal ideation

Nervous system disorders	Common	Vertigo, dizziness, headache, drowsiness
Nervous system disorders	Rare	Convulsions, tremor
Nervous system disorders	Very rare	Dysgeusia, cerebrovascular accident (stroke)
Nervous system disorders	Not known	Paraesthesia, restlessness, dystonia, dyskinesia, amnesia, memory impairment, syncope
Eye disorders	Not known	Accommodation disorder, blurred vision, mydriasis, eye pain, visual impairment, photophobia, oculogyric crisis, ischaemic optic neuropathy
Cardiac disorders	Common	Tachycardia
Cardiac disorders	Rare	Arrhythmia
Cardiac disorders	Not known	Palpitations
Vascular disorders	Rare	Pallor, arterial hypertension
Vascular disorders	Very rare	Circulatory collapse
Respiratory, thoracic and mediastinal disorders	Not known	Dyspnoea
Gastrointestinal disorders	Common	Dry mouth, nausea
Gastrointestinal disorders	Rare	Vomiting
Gastrointestinal disorders	Not known	Ischaemic colitis, diarrhoea, abdominal discomfort
Hepatobiliary disorders	Rare	Abnormal hepatic function including elevations in transaminases, alkaline phosphatases, gamma-GT and bilirubin
Skin and subcutaneous tissue disorders	Rare	Dry skin, rash, sweating increased, urticaria
Skin and subcutaneous tissue disorders	Very rare	Angioneurotic oedema, fixed drug eruption
Skin and subcutaneous tissue disorders	Not known	Acute generalized exanthematous pustulosis, pruritus
Musculoskeletal and connective tissue disorders	Not known	Arthralgia, myalgia
Renal and urinary disorders	Rare	Dysuria
Renal and urinary disorders	Not known	Urinary retention, enuresis
Reproductive system and breast disorders	Not known	Erectile dysfunction
General disorders and administration site conditions	Common	Asthenia
General disorders and administration site conditions	Not known	Oedema, malaise

Isolated cases of hepatitis have been reported when cetirizine alone is administered. After drug discontinuation, pruritus has been reported in some patients.

Reporting of suspected adverse reactions: Healthcare professionals are encouraged to report suspected adverse reactions to the Pharmacy and Poisons Board Pharmacovigilance Electronic Reporting System (PvERS): https://pv.pharmacyboardkenya.org

4.9 Overdose

Pseudoephedrine overdose: Symptoms of severe overdose can include vomiting, mydriasis, tachycardia, arrhythmia, hypertension, signs of CNS depression such as sedation, apnoea, loss of

consciousness, cyanosis and cardiovascular collapse, or CNS stimulation such as insomnia, hallucinations, tremors, convulsions that can be fatal. Treatment should be symptomatic and supportive, preferably in hospital. If spontaneous vomiting does not occur, it should be induced and gastric lavage is recommended. Activated charcoal and saline cathartics may be useful after vomiting. Usual supportive measures should be undertaken, including frequent monitoring of vital signs. Sympathomimetic amines should not be used. Hypertension should be controlled with an alpha-adrenergic blocking agent and tachycardia with a beta-adrenergic blocker. Epileptic seizures may be treated with intravenous diazepam. Cetirizine and pseudoephedrine are poorly eliminated by haemodialysis.

Cetirizine overdose: Sedation can be a symptom of overdose and appears with a single dose of 50 mg upwards. There is no specific antidote. In massive overdose, gastric lavage should be performed as soon as possible. Usual supportive measures should be undertaken with frequent monitoring of vital signs.

Reporting of suspected adverse reactions: Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to the National Regulatory Authority via the PPB reporting portal, PvERS https://pv.pharmacyboardkenya.org/

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Nasal decongestants for systemic use. ATC code: R01BA52.

The pharmacodynamic activity of cetirizine-pseudoephedrine is directly related to the effects of its active constituents.

Cetirizine: Cetirizine acts as an H1-antagonist devoid of significant anticholinergic and anti-serotonin effects. It shows some inhibition of effects of exogenous histamine, and inhibits eosinophil migration. It also reduces allergic reaction caused by specific antigens without objective effects on the central nervous system.

Pseudoephedrine: Pseudoephedrine, a stereoisomer of ephedrine, is an orally active sympathomimetic with alpha-mimetic effects greater than beta-mimetic activity. Due to its vasoconstrictor action, it has a decongestant effect on nasal mucosa. At recommended doses it can induce other sympathomimetic effects such as a rise in blood pressure, tachycardia or symptoms of central excitation such as insomnia.

5.2 Pharmacokinetic properties

Cetirizine is rapidly and almost completely absorbed after oral administration. Under fasting conditions, peak plasma concentrations are generally achieved after one hour. The degree of absorption is not reduced by food, although the rate of absorption is slowed and peak concentrations do not appear until three hours after administration. Cetirizine is not subject to appreciable metabolism during first hepatic passage. After repeated oral administration, daily urinary excretion of unchanged cetirizine is approximately 65% of the administered dose. Absorption and elimination are independent of dose. The plasma half-life is approximately nine hours and increases in patients with renal insufficiency. Cetirizine is highly bound to plasma proteins (93%).

Pseudoephedrine is rapidly and completely absorbed after oral administration. The sustained release form allows maximum plasma concentrations to be reached after eight hours. Between one quarter

and one half of the administered dose is transformed in the liver by N-demethylation into an active metabolite, nor-pseudoephedrine. This metabolite and the remaining non-metabolised pseudoephedrine are excreted in urine. Urinary excretion is increased if urine pH is decreased and decreased in cases of urinary alkalinisation. On repeated oral administration every 12 hours, steady state is reportedly reached after six days and the half-life is estimated as 15 hours. There is no reported evidence of a significant pharmacokinetic interaction between cetirizine and pseudoephedrine.

Special populations: Dosing adjustment is necessary in patients with moderate or severe renal impairment; see section 4.2.

5.3 Preclinical safety data

Reported animal studies demonstrated no toxic effect levels at 40 mg/kg/day in cynomolgus monkeys and at 30 mg/kg/day in rats after repeated administration of cetirizine. A no-effect level of 40 mg/kg/day was established in reported reproduction toxicity studies in rats. Reported reproductive toxicity studies with pseudoephedrine at oral doses up to 160 mg/kg/day in male and female rats showed no impairment of fertility, no teratogenicity and no effect on developmental parameters at clinically relevant doses. Pseudoephedrine reportedly affected spermatogenesis in rats after intraperitoneal administration at five-fold the maximum human recommended dose based on allometric scaling. No carcinogenicity studies have been reported with pseudoephedrine in combination with cetirizine. The cetirizine/pseudoephedrine combination is neither mutagenic nor clastogenic and is considered unlikely to present a carcinogenic risk for humans based on available data.

6. Pharmaceutical particulars

6.1 List of excipients

- Lactose monohydrate
- Hydroxypropyl methylcellulose / hypromellose
- Ethyl cellulose
- Isopropyl alcohol
- Purified talc
- Magnesium stearate
- Colloidal silicon dioxide
- Microcrystalline cellulose
- Maize starch
- Quinoline yellow lake
- Sodium lauryl sulphate
- Povidone K30
- Sodium starch glycolate
- Basic butylated methacrylate copolymer
- Ethyl cellulose
- Dibutyl phthalate
- Acetone
- Titanium dioxide
- Polyethylene glycol 6000
- Purified water

6.2 Incompatibilities

Cetrizet-D (cetirizine and pseudoephedrine) can interact with monoamine oxidase inhibitors (MAOIs), alcohol, and other central nervous system depressants. It may also conflict with certain health conditions like high blood pressure or glaucoma.

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store up to 30°C, protected from light. Keep all medicines out of reach of children.

6.5 Nature and contents of container
Cetrizet D is available as an aluminium strip of 10 tablets.

6.6 Special precautions for disposal and other handling
No special requirements are provided in the package insert.

7. Marketing authorization holder
Manufacturer: Sun Pharma Laboratories Ltd., 6-9 EPIP, Kartholi, Bari Brahmana, Jammu - 181 133, J & K, India.

8. Marketing authorization number
14004 - 7507

9. Date of first authorization/renewal of the authorization
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10. Date of revision of the text
June 2026