Himalaya®
HERBAL HEALTHCARE

SUMMARY OF THE PRODUCT CHARACTERISTICS

1. **Trade name of the Medicinal product: Cystone (Uncoated tablets)**

2. **Composition:**

Each 223 mg contains active ingredients:

Exts.	Shilapushpa	*Didymocarpus pedicellata*	65 mg
	Pasanabheda	*Saxifraga ligulata*	49 mg
	Manjishtha	*Rubia cordifolia*	16 mg
	Nagaramusta	*Cyperus scariosus*	16 mg
	Apamarga	*Achyranthes aspera*	16 mg
	Gojiha	*Onosma bracteatum*	16 mg
	Sahadevi	*Vernonia cinerea*	16 mg
Pdrs.	Shilajeet (Purified)[$]	-	13 mg
	Hajrul Yahood bhasma	Lime silicate calx	16 mg

[$] Non herbal preparation

Which are processed over the steam of extract of the following herbal materials mixture Vanatulasi (*Ocimum basilicum*), Kulattha (*Dolichos biflorus*), Gokshura (*Tribulus terrestris*), Lajjalu (*Mimosa pudica*), Balam (*Pavonia odorata*), Joratoota (*Equisetum arvense*) and Shaka seed (*Tectona grandis* seed).

Processed with:

Microcrystalline cellulose	18.00 mg
Carmellose sodium	4.00 mg
Inactive ingredients:	
Microcrystalline cellulose	45.00 mg
Crospovidone	3.00 mg
Cabosil M5	3.00 mg
Sodium carboxy methylcellulose	2.00 mg
Magnesium stearate	2.00 mg

3. **Pharmaceutical form:** Tablets

4. Clinical particulars:

4.1 Therapeutic indications:

a. Urolithiasis:
- Oxalate stones
- Phosphate stones
- Uric acid and urate calculi
- Crystalluria
- Prevents post-operative recurrence of calculi
- Mixed crystals – glycolic acid

b. As an adjuvant in:
- Urinary tract infections
- Urinary tract infections during pregnancy
- Non-specific urethritis
- Cystitis, pyclitis
- Burning micturition
- Gout and hyperuricemia

c. Urgency, incontinence of urine in women

d. Sialolithiasis

4.2 Posology and Method of administration:

In adults

In urolithiasis and crystalluria:

2 tablets three times daily for 3 to 4 months, followed by 1 tablet twice daily till the stone passes out.

Urinary infections: 2 tablets three times daily depending on the severity, until the infection is cleared.

Burning micturition: 2 tablets three times daily for 4 days to 2 weeks or till symptoms subside.

To prevent recurrence after surgical removal or passage: 1 tablet thrice daily for 4 to 5 months

In children

6-11 years: 1 tablet thrice daily

12-15 years: 1 tablet four times a day

Route of administration : Oral

4.3 Pharmacotherapeutical group : Other urologicals

4.4 Contraindications : Children under 6 years of age

4.5 **Special warnings and Precautions:** Cystone administration is not advisable in case of threatening urethra obstruction due to large size of concrements; Cystone intake is recommended simultaneously with increased consumption of liquid – up to 2-2.5 liters per day.

4.6 **Interactions with other drugs** : None

4.7 Pregnancy and Lactation : During pregnancy and lactation period Cystone might be used according to physician's prescriptions only, when according to physician's opinion, benefit after intake of the drug exceeds potential risks for fetus and child.

4.8 **Administration in children** : Contraindicated in children under 6 years of age

4.9 **Undesirable effects** : Allergic reactions and dyspeptic disorders are possible

4.10 **ATC code** : G04BX

4.11 **Distribution conditions** : On prescription

5. Pharmacological properties

5.1 Pharmacodynamic properties:

Cystone prevents supersaturation of lithogenic substances, controls oxamide absorption from the intestine (a substance that precipitates stone formation) and corrects crystalloid-colloid imbalance. It inhibits calculogenesis by reducing the stone forming substances like oxalic acid, calcium hydroxyproline etc and causes its expulsion by micropulverization. Cystone causes disintegration of the calculi and the crystals by acting on the mucin, which binds the particles together. Its antimicrobial activity is beneficial in the treatment of urinary tract infections. Its antispasmodic and anti-inflammatory activity relieves ureteric colic and alleviates symptoms of burning and painful micturition.

5.2 Pharmacokinetic properties:

Since Cystone is a poly-herbal formulation, more than one constituent is responsible for the activity. The formulation owes its activity to the synergistic actions of its ingredients. Since a single chemical entity is not responsible for the activity, the pharmacokinetic studies of Cystone are not feasible.

5.3 **Preclinical safety data:**

No mortality of animals was observed with single oral administration of Cystone at a dose of 5000 mg/kg. Hence the median lethal dose (LD_{50}) was found to be greater than 5000 mg/kg b.wt. p.o. Cystone administration was found to be safe following oral administration for 90 days in rats (subchronic). The no observed adverse effect level (NOAEL) was found to be greater than 3000 mg/kg b.wt. Embryo toxicity and peri- and post-natal toxicity studies revealed that Cystone tablet is devoid of any toxic effects during gestation and lactation in rats. In vitro mutagenicity study with Cystone tablets using bacterial reverse mutation test revealed no mutagenicity. The above findings support that Cystone is completely safe and is devoid of any adverse effects.

6. **Pharmaceutical particulars**

6.1 **List of excipients expressed qualitatively**

Magnesium stearate	Ph.Eur.#
Sodium carboxymethylcellulose	Ph.Eur.#
Microcrystalline cellulose	Ph.Eur.#
Crospovidone	Ph.Eur.#
Colloidal silicon dioxide	Ph.Eur.#

#Ph.Eur. : European Pharmacopoeia

6.2 **Incompatibilities:**

The excipients used for the formulation does not cause any physical, chemical and pharmacological incompatibility with active materials. This was proved by the chromatographic analysis.

6.3 **Shelf life:**

Shelf life in the product as packaged for sale : 3 years

Shelf life after first opening the container : Not applicable

6.4 **Special precautions for storage** : Store in a dry place, at temperature not exceeding 30°C: Keep out of reach of children.

6.5 Nature and contents of container : White HDPE bottles with Screw cap lid

6.6 **Instructions for use / handling** : None

7. **Marketing authorization holder** : In India – The Himalaya Drug Company

8. Marketing authorization number: In India – Mfg.Lic.Aus-83

For THE HIMALAYA DRUG COMPANY