Summary of Product Characteristics for Pharmaceutical Products

1. Name of the Medicinal Product.

Super Apeti Syrup (Cyproheptadine Syrup)

2. Qualitative and Quantitative Composition

Each 5 ml contains:

Cyproheptadine Hydrochloride BP 2 mg

Flavored syrup base..... Q. S

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

Syrup (Oral)

A Yellow colored clear fruity flavored free flowing homogeneous liquid. Clear colorless liquid without any visible impurities.

4. Clinical particulars

4.1 Therapeutic indications

Super Apeti is indicated in the treatment of

- Perennial and seasonal allergic rhinitis
- Vasomotor rhinitis
- Allergic conjunctivitis due to inhalant allergens and foods
- Mild, uncomplicated allergic skin manifestations of urticaria and angioedema
- Amelioration of allergic reactions to blood or plasma
- Cold urticaria
- As therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled.

4.2 Posology and method of administration

Route of Administration: Oral

Dosage:

There is no recommended dosage schedule for children under two years of age. Dosage must be individualized. Since the antiallergic effect of a single dose usually lasts four to six hours, the daily requirement should be given in divided doses three times a day or as often as necessary to provide continuous relief.

Age 2 to 6 years: The usual dose is 2 mg (one teaspoonful) two or three times a day, adjusted as necessary to the size and response of the patient. The dose is not to exceed 12 mg a day.

Age 7 to 14 years: The usual dose is 4 mg (two teaspoonfuls) two or three times a day, adjusted as necessary to the size and response of the patient. The dose is not to exceed 16 mg a day.

Adults: The therapeutic range is from 4mg to 20mg a day, the majority of patients requiring 12mg to 16mg a day. An occasional patient may require as much as 32mg a da y for adequate relief. It is suggested that dosage be initiated with 4mg (two teaspoonfuls) three times a day and adjusted according to the size and response of the patient. The dosage is not to exceed 32mg a day.

4.3 Contraindications

Newborn or Premature Infants: This drug should not be used in newborn or premature infants.

Nursing Mothers: Because of the higher risk of antihistamines for infants generally and for newborns and prematures in particular, antihistamine therapy is contraindicated in nursing mothers.

Other Conditions:

Hypersensitivity to cyproheptadine and other drugs of similar chemical structure

Monoamine oxidase inhibitor therapy (see Drug Interactions)

Angle-closure glaucoma

Stenosing peptic ulcer

Symptomatic prostatic hypertrophy

Bladder neck obstruction

Pyloroduodenal obstruction

Elderly, debilitated patients

4.4 Special warnings and precautions for use

Children: Overdosage of antihistamines, particularly in infants and children, may produce hallucinations, central nervous system depression, convulsions and death.

Antihistamines may diminish mental alertness; conversely, particularly in the young child, they may occasionally produce excitation.

CNS Depressants: Antihistamines may have additive effects with alcohol and other CNS depressants, e.g., hypnotics, sedatives, tranquilizers, antianxiety agents.

Activities Requiring Mental Alertness: Patients should be warned about engaging in activities requiring mental alertness and motor coordination, such as driving a car or operating machinery.

Antihistamines are more likely to cause dizziness, sedation and hypotension in elderly patients.

Cyproheptadine has an atropine-like action and, therefore, should be used with caution in patients with: History of bronchial asthma, Increased intraocular pressure, Hyperthyroidism, Cardiovascular disease, Hypertension.

4.5 Interaction with other medicinal products and other forms of interaction.

MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines. Antihistamines may have additive effects with alcohol and other CNS depressants, e.g. hypnotics, sedatives, tranquillizers and anti-anxiety agents. Drugs with anti-serotonin activity, such as cyproheptadine, may interfere with serotonin- enhancing anti-depressants including selective serotonin re-uptake inhibitors (SSRI's). This may result in possible recurrence of depression and related symptoms. Cyproheptadine may cause a false positive test result for tricyclic antidepressant drugs (TCA) when evaluating a drug screen (e.g. urine, serum). Because cyproheptadine and TCAs may produce similar overdose symptoms, physicians should carefully monitor patients for TCA toxicity in the event of combined overdose.

4.6 Fertility, pregnancy and Lactation

The use of any drug in pregnancy or in women of childbearing potential require that the anticipated benefit be weighed against possible hazard to the embryo or Foetus. There are insufficient data to evaluate the possible harmfulness of this substance when used in human pregnancy.

4.7 Effects on ability to drive and use machines

Patients should be warned about engaging in activities requiring mental alertness and motor coordination, such as driving a car or operating machinery.

4.8 Undesirable effects.

The side effects that appear frequenly are drowsiness and somnolence. Many patients who complain initially of drowsiness may no longer do so after the first

three or four days of continuous administration. Adverse reactions, which have been reported with the use of antihistamins are as follows:

- **Central nervous system:** Sedation, sleepness (often transient), dizziness, disturbed coordination, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, paresthesia, neurtitis, convulsion, euphoria, hallucination,faintness.
- **Integumentary:** Allergic manifestation of rash and edema, excessive perspiration, urticaria, photosensitivity.
- **Special Senses:** Acutelabyrinthitis, blurred vision, duokioua,vertigo, tinnitus.
- **Cardiovascular:** Hypotension, palpitation, tachycardia, extrasystoles, anaphylactic shock.
- **Hematologic:** Hemolytic anemia, leukopenia, agranulocytosis, thrombocytopenia.
- **Digestive System:** Dryness of mouth,epigastric distress.
- **Genitourinary:** Frequency of micturition, difficult micturition, urinary retention, early menses.
- **Respiratory:** Dryness of nose and throat, thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness

Miscellaneous: Fatigue, chills and headache

Reporting of suspected adverse reactions.

Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org '

4.9 Overdose

Antihistamines overdosage reactions may vary from central nervous system depression or stimulation to convulsion and death, especially in infants and children.Also, atropine- like signs and symptoms (dry mouth, fixed, dilated pupils, hallucinations, flushing, etc) as well as gastrointestinal symptoms may occur.

If vomiting has not occurred spontaneously the patient should be induced to vomit if conscious. If the patient is unable to vomit, perform gastric lavage with isotonic or half isotonic saline. This should be followed by administration of active charcoal, suspended in a solution with laxative activity, such as saline cathartics, sodium sulphate or magnesium hydroxide.

Adequate precautions against aspiration should be taken at all times. Saline cathartics draw water in to the bowel by osmosis and therefore are valuable for their action in rapid dilution of bowel contents. Volume repletion may be used in hypotension, possibly supplemented with administration of catecholamines. In exceptional cases, when life threatening CNS signs are present, intravenous physostigmine salicylate may be considered. Dosage and frequency of

administration are dependent on age, clinical response and recurrence after response.

5.Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Super Apeti is an antihistaminic (antiallergic) and Anti-serotonergic agent.

ATC Code: R06AX02

Cyproheptadine is a piperidine H1-antagonist. Unlike other H1-antagonists,this drug also antagonizes serotonin receptors. This action makes cyproheptadine useful in conditions such as Cushing's syndrome, vascular headache and anorexia. Cyproheptadine has also been used for the management of anorgasmy caused by antidepressants such as SSRIs; however, it must be monitored closely when used for this purpose since the antidepressant effects for the SSRI may also be reversed. In a small study, patients with chronic urticaria ranked cyproheptadine higher than five other H1-antagonists in efficacy and freedom from side effects.

5.2 Pharmacokinetic properties.

Cyproheptadine is administered orally. In general, H1-blockers are well absorbed from the GI tract, but they vary insolubility, which ultimately affects the onset of action. Less soluble H1-antagonists have a slower onset of action and are less likely to cause toxicity; cyproheptadine has moderate solubility. Peak concentration of cyproheptadine occurs in about 6-9 hours and the duration of action is about 8hours.Distribution of cyproheptadine has not been elucidated and it is unknown if the drug is distributed into milk. The parent compound is extensively metabolized in the liver to a number of conjugated metabolites. Plasma half-life ranges from 1-4 hours. Excretion is mainly renal, with no apparent excretion of unchanged drug. Some unchanged drug and metabolites are excreted in feces.

5.3 Preclinical safety data

None Known

6.Pharmaceutical particulars

6.1 List of excipients

- Methyl Hydroxybenzoate BP

- Propyl Hydroxybenzoate BP
- Sucrose BP
- Saccharine Sodium BP
- Propylene Glycol BP
- Liquid Sorbitol BP
- Citric Acid Monohydrate BP
- Colour Tartrazine Supra IH
- Lemon Flavour
- Mixed Fruit Delux Flavour IH

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C, do not freeze. Store in a dry and dark place. Keep out of the reach of children.

6.5 Nature and contents of container

Available in bottles of 100ml in individual boxes.

No special requirements for disposal and other handling.

7. Marketing Authorization holder

Shalina Healthcare Dmcc

30th Floor, Almas Towers,

8.Marketing authorization number(s)

H2001/49

9.Date of first authorization/renewal of the authorization

22/01/2026

10. Date of revision of the text

22/01/2026