

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. Name of the medicinal product

**Apitol Syrup (Cyproheptadine HCL B.P 2mg/5ml)**

### 2. Qualitative and quantitative composition

Cyproheptadine Syrup:

Each 5ml of syrup contains Cyproheptadine HCL equivalent to Cyproheptadine 2mg BP in flavoured syrupy base.

For the full list of excipients, see section 6.1.

### 3. Pharmaceutical form

Syrup

Cyproheptadine Syrup:

Light orange colored syrup , having pleasant odour and sweet taste.

### 4.0 Clinical particulars

#### 4.1 Therapeutic indications

Cyproheptadine 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

Children: The total daily dosage for children may be calculated on the basis of body weight or body area using approximately 0.25 mg/kg/day (0.11 mg/lb/day) or 8 mg per square meter of body surface (8 mg/m<sup>2</sup>).

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 teaspoonsful) 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.

Apitol is administered by mouth.

#### **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

#### **PRECAUTIONS**

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, tranquillisers 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**

##### Pregnancy

For ascorbic acid no clinical data on exposed pregnancies are available. Animal studies do not indicate direct or harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Pregnant women should exercise caution.

##### Breast-feeding

It is not known whether Apitol Syrup is excreted in human milk, and because of the potential for serious adverse reactions in breast-feeding infants from Apitol syrup, a decision should be made whether to discontinue breast-feeding or to discontinue the drug, taking into account the importance of the drug to the mother.

#### **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.

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

#### **4.8 Undesirable effects**

Adverse reactions which have been reported with the use of antihistamines are as follows:

Central Nervous System: Sedation and sleepiness (often transient), dizziness, disturbed coordination, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, paresthesias, neuritis, convulsions, euphoria, hallucinations, hysteria, faintness.

Integumentary: Allergic manifestation of rash and edema, excessive perspiration, urticaria, photosensitivity.

Special Senses: Acute labyrinthitis, blurred vision, diplopia, vertigo, tinnitus.

Cardiovascular: Hypotension, palpitation, tachycardia, extrasystoles, anaphylactic shock.

Hematologic: Hemolytic anemia, leukopenia, agranulocytosis, thrombocytopenia.

Digestive System: Dryness of mouth, epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation, jaundice.

Genitourinary: Urinary frequency, difficult urination, urinary retention, early menses.

Respiratory: Dryness of nose and throat, thickening of bronchial secretions, tightness of chest and wheezing, nasal stuffiness.

Miscellaneous: Fatigue, chills, headache, increased appetite/weight gain.

### **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.

### **4.9 Overdose**

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

If vomiting has not occurred spontaneously, the patient should be induced to vomit with syrup of ipecac.

If the patient is unable to vomit, perform gastric lavage followed by activated charcoal. Isotonic or 1/2 isotonic saline is the lavage of choice. Precautions against aspiration must be taken especially in infants and children. When life-threatening CNS signs and symptoms are present, intravenous physostigmine salicylate may be considered. Dosage and frequency of administration are dependent on age, clinical response and recurrence after response.

## **5.0 Pharmacological properties**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Anti-histamine

Cyproheptadine hydrochloride is a serotonin and histamine antagonist with anticholinergic and sedative effects. Antiserotonin and antihistamine drugs appear to compete with serotonin and histamine, respectively, for receptor sites.

The inhibitory effect of cyproheptadine in histamine-induced gastric secretion is also unusual as specific anti-histamines do not influence this effect.

## **5.2 Pharmacokinetic properties**

After a single 4 mg oral dose of <sup>14</sup>C-labeled cyproheptadine HCl in normal subjects, given as tablets or syrup, 2-20% of the radioactivity was excreted in the stools. Only about 34% of the stool radioactivity was unchanged drug, corresponding to less than 5.7% of the dose. At least 40% of the administered radioactivity was excreted in the urine. No detectable amounts of unchanged drug were present in the urine of patients on chronic 12-20 mg daily doses of cyproheptadine syrup. The principal metabolite found in human urine has been identified as a quaternary ammonium glucuronide conjugate of cyproheptadine. Elimination is diminished in renal insufficiency.

## **5.3 Preclinical safety data**

There are no other preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## **6.0 Pharmaceutical particulars**

### **6.1 List of excipients**

Sucrose, Sodium benzoate, Di-sodium EDTA, Sorbitol 70%, liquid glucose, glycerine, banana flavour, sunset yellow, purified water

### **6.2 Incompatibilities**

None

### **6.3 Shelf life**

2 years

### **6.4 Special precautions for storage**

This medicinal product does not require any special storage conditions.

Store this medicine at temperature below 30°C and keep away from children.

### **6.5 Nature and contents of container**

100 ml and 200ml amber PET bottle with a P.P cap having Me Cure print.

### **6.6 Special precautions for disposal and other handling**

None

### **7.0 Marketing authorization holder**

Me Cure Industries Limited  
Plot 6 Block H Debo Industries Compound,  
Oshodi Industrial Scheme,  
Oshodi,  
Lagos,  
Nigeria.

**8.0 Marketing Authorisation Number**  
NAFDAC NO: A4-4942