# MECURE INDUSTRIES PLC

# SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. Name of the medicinal product

**APITOL TABLETS (Cyproheptadine Hydrochloride B.P 4mg)**

## 2. Qualitative and quantitative composition

*Cyproheptadine Tablets:*

Each tablet contains Cyproheptadine Hydrochloride equaivalent to anydrous Cyproheptadine 4mg BP

For the full list of excipients, see section 6.1.

## 3. Pharmaceutical form

Tablets

*Cyproheptadine tablet:*

White round uncoated tablet with breakline on one side and 'MECURE' on the other side

## 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

*Allergies and pruritus*
Adults: Take 1 tablet, 3 times a day, as required. Do not take more than 8 tablets in 24 hours.
Children (7 - 14 years): Take 1 tablet, 3 times a day as required. Do not take more than 4 tablets in 24 hours.
Children (2 - 6 years): Take 5ml syrup, two to three times a day. Do not give more than 30ml in 24 hours.
*Migraine and vascular types of headaches*

Adults: Take 1 tablet initially. If required, take a second tablet after 30 minutes. Do not take more than 2 tablets every 4-6 hours.

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 14C-labeled cyproheptadine HCI 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

Starch, PVPK30, lactose, Di-Calcium Phosphate, Talcum powder, Magnesium stearate, Sodium starch glycolate.

### 6.2 Incompatibilities

None

### 6.3 Shelf life

3 years

### 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

Store this medicine at temperature below $30^0$C and keep away from children.

### 6.5 Nature and contents of container

Blister pack of 2 x 10

### 6.6 Special precautions for disposal and other handling

None

## 7.0 Marketing authorization holder

Me Cure Industries PLC
Plot 6 Block H Debo Industries Compound,
Oshodi Industrial Scheme,
Oshodi,
Lagos,

Nigeria.

**8.0 NAFDAC Registration Number**: A4-3376