1.3 PRESCRIBING INFORMATION

1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 Name of the Medicinal Product

APETATRUST

[Cyproheptadine with Multivitamin Syrup]

1.2 Strength

As shown in below composition

1.3 Pharmaceutical Form

Oral Liquid Syrup

A Yellow colour

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Cyproheptadine HCL BP	2 mg
Lysine HCl BP	150 mg
Vitamin B1 BP	5 mg
Vitamin B2 BP	1.5 mg
Vitamin B6 BP	1.5 mg
Niacinamide BP	7.5 mg
Zinc Sulfate monohydrate BP	7.5 mg
Manganese Sulfate BP	0.8 mg
Flavoured Syrupy Base	q.s.

3. PHARMACEUTICAL FORM

Liquid Syrup for oral use

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Appetite stimulant & Dietary Supplement

4.2. Posology and method of administration

Route of administration: Oral

APETATRUST is used in adults and children

Dosage:

Adult: one teaspoonful (5ml) twice in a day.

Children: As directed by physician.

4.3. Contra-indications

APETATRUST should not be used by patients with pre-existing hypervitaminosis D or with impaired renal function, iron accumulation and iron utilisation disorders, hypercalcaemia or hypercalciuria, and hypersensitivity to any ingredient of the product.

4.4. Special warnings and special precautions for use

Precautions

General

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

WARNINGS

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

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

CNS Depressant

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

4.5. Interactions with other Drug 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, tranquilizers, antianxiety agents

4.6. Pregnancy and lactation

Use in lactation

The recommended dosage should not be exceeded and the APETATRUST should not be taken together with other medicines or dietary supplements containing Vitamin D or iron in order to avoid overdosage of these.

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 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 apglassite/weight gain.

4.9 Overdose

In the event of overdosage occurring, an emetic should be administered as soon as possible, followed by gastric lavage if indicated. Immediately following emesis, a large dose of a saline cathartic should be used to speed passage through the intestinal tract.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Cyproheptadine is serotonin and histamine antagonist with anticholinergic and sedative effects. Antiserotonin and antihistamine drugs appear to comglasse with serotonin and histamine, respectively, for receptor sites. Multivitamin preparation specially designed to ensure a valuable Micronutrient supply.

Vitamins are essential nutrients. They are indispensable for the normal development and growth of the foetus and the infant, for the metabolism and formation of carbohydrates, energy, lipids,

nucleic acids and proteins, as well as for the synthesis of amino acids, collagen and neurotransmitters.

Multivitamins preparations are indicated to maintain the micronutrient nutritional requirements. Pregnancy and lactation represent periods with increased micronutrient requirements and, as a consequence, increased risks of micronutrient deficiencies for both the mother and the child. Especially during pregnancy, micronutrient deficiencies exhibit a more serious health risk, as they may also impair the normal development of the unborn child.

5.2 Pharmacokinetic Properties

After a single 4 mg oral dose of 14C-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 significant difference in the mean urinary excretion exists between the tablet and syrup formulations. No detectable amounts of unchanged drug were present in the urine of patients on chronic 12-20 mg daily doses of cyproheptadine syrup. The principle 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

Not Applicable

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Citric Acid Monohydrate
Glycerin
Pineapple Supreme Flavour
Propylene Glycol
Sodium Benzoate
Sodium Saccharine
Sodium Hydroxide Pellets
Sodium Methyl Paraben
Sodium Propyl Paraben
Sorbitol Solution 70%
Purified Water

6.2. Incompatibilities

Not applicable

6.3. Shelf life

24 Months

6.4 Special precautions for storage

Storage below 30^{o}C, Protected from the sunlight.

Keep out of reach and sight of children.

6.5. Nature and contents of container

1 x 200 ml Amber colour Glass Bottle

6.6. Instruction for use and handling

No special requirements

7. APPLICANT

PHARMATRUST LTD.

Accra, Ghana

8. FDA APPLICATION NUMBER

Not Applicable

9. DATE OF REGISTRATION / RENEWAL OF REGISTRATION

FDA/SD.183-5378

10. DATE OF REVISION OF THE TEXT

Oct 2017