APPENDIX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
FORTIGEN syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Cyproheptadine HCL ..... 2.0 mg
Vitamin B2 ..... 0.5 mg
Vitamin B6 ..... 0.5 mg
Vitamin B1 ..... 1.0 mg
Nicotinamide ..... 10.0 mg
Vitamin B12 ..... 1.0 mcg
For 5 ml
Excipients: sucrose.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
oral syrup

4. CLINICAL DATA

4.1. Therapeutic indications
FORTIGEN syrup is indicated as an appetite stimulant.

4.2. Dosage and method of administration
Dosage
The dosage should be individualized according to the needs and reactions of the patient.
For information :
children
2 to 6 years: 1/2 (2.5 ml) to 1 teaspoon (5 ml) two or three times a day. 7 to 14 years old: 2 teaspoons (10 ml) two or three times a day Adolescents and adults
2 teaspoons (10 ml) 3 times a day.
Administration mode
Oral use

4.3. Contrindications
Contraindicated in patients known to be hypersensitive to any of its components and in patients with hypervitaminosis.
This medication should not be used in newborns or premature infants, or in children under 2 years of age. Due to the higher risk of non-adoption of antihistamines for infants in general and for Newborns and premature babies in particular, antihistamine treatment is contraindicated in nursing mothers.

Contraindicated in case
- hypersensitivity to cyproheptadine HCl and other drugs with similar chemical structure
- treatment with monoamine oxidase inhibitor (MAO)
- angle-closure glaucoma

- stenosing peptic ulcer
- symptomatic prostatic hypertrophy
- obstruction of the bladder neck
- pyloroduodenal obstruction
- in the elderly and weak

4.4. Special warnings and precautions for use

related to Cyproheptadine

Cyproheptadine HCL has a similar action to atropine and, therefore, should be used with caution in patients with:
- a history of bronchial asthma - increased intraocular pressure
- hyperthyroidism
- cardiovascular disease
- hypertension

In pediatric patients

An overdose of antihistamines, especially in infants and young children, can produce hallucinations, central nervous system depression, seizures, cardiac and respiratory arrest, and death. Antihistamines may decrease alertness; conversely, especially in young children, they can sometimes produce excitement.

CNS depressants

Antihistamines can have cumulative effects with alcohol and other CNS depressants, such as hypnotics, sedatives, tranquilizers, and anti-anxiety agents.

Activities requiring vigilance

Patients should not engage in activities requiring alertness and motor coordination, such as driving a car or operating machinery. Antihistamines may cause dizziness, sedation and hypotension in elderly patients (see warnings and precautions, geriatric use).

related to Vitamin, B1, B2, B6, B3 and B12

Multivitamins are not recommended for the treatment of serious vitamin and mineral deficiencies. In such cases, the underlying cause should be determined and corrected if possible.
The intake of vitamins must accompany a complete diet, namely absorption of protein and daily energy. No other vitamin, mineral or dietary supplement with or without vitamin A should be taken with this preparation, except under medical supervision.

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 central nervous system (CNS) depressants, for example, hypnotics, sedatives, tranquilizers, and anti-anxiety agents.

4.6. Pregnancy and breast feeding

Category B pregnancy

Reproduction studies have been performed in rabbits, mice and rats with oral or subcutaneous doses up to 32 times the maximum recommended oral dose for humans. The results indicated no decrease in fertility or negative fetal consequences due to HCL cyproheptadine. Cyproheptadine HCl has been shown to be fetotoxic in rats when administered by intraperitoneal injection at doses four times the maximum recommended oral dose for humans. Two studies in pregnant women, however, have not shown that cyproheptadine hydrochloride increases the risk of abnormalities when administered
during the first, second and third trimesters of pregnancy. No teratogenic effects have been observed in neonates. However, since studies in humans cannot exclude the possibility of harm, cyproheptadine HCl should only be used during pregnancy if necessary.

Breast feeding
It is currently impossible to know if this drug is excreted in human milk. As many drugs are excreted in breast milk, and due to the risk of serious adverse reactions in infants who would take cyproheptadine HCl, a decision should be made whether to discontinue breast-feeding or to discontinue the drug, taking into account the degree of necessity of the drug for the mother (see contraindications).

4.7. Effects on ability to drive and use machines
Not applicable

4.8. Side effects

In general multivitamins are well tolerated by the body. Sometimes reactions can occur, but they go away quickly with continuous and regular use.
The side effects that have been reported with the use of antihistamines are as follows:

Central nervous system
Sedation and drowsiness (often transient), dizziness, disturbed coordination, confusion, agitation, excitement, nervousness, tremors, irritability, insomnia, paraesthesia, neuritis, convulsions, euphoria, hallucinations, hysteria and fainting.

Integumentary
Allergic manifestation with rash and edema, excessive sweating, hives and photosensitivity.

Sensory disturbances
Acute Labyrinthitis, blurred vision, diplopia, vertigo and tinnitus.

Cardiovascular
Hypotension, palpitations, tachycardia, extrasystoles and anaphylactic shock.

Hematology
Hemolytic anemia, leukopenia, agranulocytosis and thrombocytopenia.

Digestive system

Cholestasis, liver failure, hepatitis, abnormal liver function, dry mouth, epigastric pain, anorexia, nausea, vomiting, diarrhea, constipation and jaundice.

Genitourinary
Urinary frequency, difficult urination, urinary retention, onset of menstruation.

Respiratory
Dry nose and throat, thickening of bronchial secretions, tightness in the chest, wheezing and nasal congestion.

Various
Fatigue, chills, headache, increased appetite and weight gain.

The reporting of suspected adverse reactions after authorization of the medicinal product is important. It allows continuous monitoring of the benefit / risk ratio of the drug.

4.9. Overdose
Reactions to overdosage with antihistamine can range from CNS depression to stimulation, especially in pediatric patients. In addition, atropine signs and symptoms (dry mouth, fixed and dilated pupils, hot flushes, etc.) as well as gastrointestinal symptoms may occur.
If vomiting did not occur spontaneously, the patient should be encouraged to vomit with syrup Ipecac.
If the patient is unable to vomit, perform gastric lavage followed by activated charcoal. An isotonic or half-isotonic saline solution may be a washing choice. Precautions against aspiration should be taken especially in infants and children.
When there are life-threatening signs and symptoms of CNS, intravenous physostigmine salicylate may be considered. The dosage and frequency of administration depends on age, clinical response, and recurrence after the response.
Saline cathartics, like milk of magnesia, draw water from the intestine by osmosis and, therefore, are useful for their action in the rapid dilution of the contents of the intestine.
Stimulants should not be used.
Vasopressors can be used to treat low blood pressure.
The oral LD50 of cyproheptadine hydrochloride is 123 mg / kg and 295 mg / kg in mice and rats, respectively.
Information related to vitamin overdose is not available.

5. PHARMACOLOGICAL PROPERTIES
5.1. Pharmacodynamic properties

cyproheptadine
Cyproheptadine hydrochloride (HCl) is an antagonist of serotonin and histamine with anticholinergic and sedative effects. Anti-serotonin and antihistamine appear to compete with serotonin and histamine, respectively, at receptor sites.
Vitamin B2 (Riboflavin)
Riboflavin is phosphorylated to flavin mononucleotide (FMN) and flavin adenine dinucleotide (FAD), which act as co-enzymes in the respiratory chain and in oxidative

phosphorylation. Riboflavin deficiency leads to eye symptoms, as well as lesions on the lips and corners of the mouth.

Vitamin B6 (Pyridoxine)

Pyridoxine, once absorbed, is quickly converted to co-enzymes, pyridoxal phosphate and pyridoxamine phosphate, which play an essential role in protein metabolism. Convulsions and hypochromic anemia have been observed in infants deficient in pyridoxine**.**

Vitamin B1 (Thiamine)

Thiamine (as a co-enzyme, thiamine pyrophosphate) is associated with carbohydrate metabolism. Thiamine pyrophosphate also acts as a co-enzyme in the direct oxidation pathway of glucose metabolism. In case of thiamine deficiency, pyruvate and lactic acid accumulate in the tissues. The pyruvate ion is involved in the biosynthesis of acetylcholine, by its transformation into acetyl-coenzyme-A by a process dependent on thiamine. In case of thiamine deficiency, there can be consequences on the central nervous system. This can come either from the effect on the synthesis of acetylcholine or from the accumulation of lactate and pyruvate. Thiamine deficiency leads to fatigue, anorexia, gastrointestinal upset, tachycardia, irritability and neurological symptoms. A significant deficit in thiamine (and other components of the vitamin B group) can cause beriberi disease.

VitamineB3 (Niacin / Nicotinamide)

The biochemical functions of nicotinamide such as nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP) include the breakdown and synthesis of fatty acids, carbohydrates and amino acids as well as hydrogen transfer. A deficiency would produce pellagra and mental neurological changes.

Vitamin B12 (Cyanocobalamin)

Vitamin B12 is present in the body mainly as methylcobalamin, adenosylcobalamin and hydroxocobalamin. These act as co-enzymes in trans methylation from homocysteine to methionine; In the isomerization of the methylmalonyl co-enzyme into succinyl coenzyme and folate in several metabolic pathways, respectively. Vitamin B12 deficiency interferes with hemopoiesis and produces megaloblastic anemia.

5.2. Pharmacokinetic properties

cyproheptadine

After a single 4 mg oral dose of cyproheptadine hydrochloride (labeled 14C) given as tablets in normal subjects, 2 to 20% of the radioactivity is excreted in the stool. Only about 34% of the stool radioactivity is unchanged, which corresponds to less than 5.7% of the dose. At least 40% of the administered radioactivity is excreted in the urine. No unchanged substance is detected in the urine of patients on continuous daily doses of 12 to 20 mg. The main metabolite found in human urine has been identified as a quaternary ammonium glucuronide conjugated to cyproheptadine hydrochloride. Elimination is decreased in case of renal failure.

Vitamin B2 (Riboflavin)

Riboflavin is absorbed from the gastrointestinal tract and in the circulation is bound to plasma proteins. It is widely distributed. It is stored in small quantities and the excess is excreted in the urine. In the body, riboflavin is converted to FMN and then to DAF.

Vitamin B6 (Pyridoxine)
Pyridoxine is absorbed from the gastrointestinal tract and converted to pyridoxal phosphate active, which is linked to plasma proteins. It is excreted in the urine as acid 4-pyriodoxic.
Vitamin B1 (Thiamine)
Thiamine is absorbed from the gastrointestinal tract and is widely distributed in most tissues of the body. Amounts exceeding the body's requirements are not stored but excreted in the urine as unchanged thiamine or its metabolites.
VitamineB3 (Niacin / Nicotinamide)
Nicotinic acid is absorbed from the gastrointestinal tract, is widely distributed in body tissue, and has a short half-life.
Vitamin B12 (Cyanocobalamin)
Cyanocobalamin is absorbed from the gastrointestinal tract and is strongly linked to specific plasma proteins. A study with labeled vitamin B12 showed that it was quickly taken up by the intestinal mucosa and kept there for 2-3 hours. Maximum blood and tissue concentrations did not occur until 8 to 12 hours after dosing with maximum concentrations in the liver within 24 hours. Cobalamins are stored in the liver, excreted in the bile and undergo enterohepatic recycling. Part of the dose is excreted in the urine, most of it in the first 8 hours.

5.3. Preclinical safety data
Not applicable

6. PHARMACEUTICAL PARTICULARS
6.1. List of excipients
Sucrose, Sodium Methyl Paraben, Sodium Propyl Paraben, Sorbitol 70%, Sodium Hydroxide, Bronpole, Glycerin, Citric Acid, Mixed Fruit Flavor 1038, Propylene Glycol

6.2. incompatibility
Not applicable

6.3. The duration of the conversation
24 months

6.4. Special storage precautions
Store in a cool, dry place

6.5. Nature and content of outer packaging
120 ml PET bottle with measuring spoon

6.6. Special precautions for disposal and other handling
Not applicable

7. MARKETING AUTHORIZATION HOLDER
HOLDER AND OPERATOR:
FRILAB SA
17 rue des Pierres du Niton
1207 Geneva SWITZERLAND
Maker :

Athena Drug Delivery Solutions Pvt Ltd Manufactured by-Sanpras Healthcare Pvt. Ltd. At: Plot No. 81, Stice,
Musal Gaon, Sinnar-422 112

8. DOSIMETRY

Not applicable.

9. INSTRUCTIONS FOR THE PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS OF PRESCRIPTION AND DELIVERANCE

Not applicable