ANNEX 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
2-6 years: 1/2 (2.5 ml) to 1 teaspoon (5 ml) two or three times daily. 7 to 14 years: 2 teaspoons (10 ml) two or three times a day
Adolescents and adults
2 teaspoons (10 ml) 3 times a day

Administration mode
Oral way

4.3. Cons-indications
Contraindicated in patients known to be hypersensitive to any of its components and in patients with hypervitaminosis.
This drug should not be used in infants or preterm infants, or children under 2 years. Because of the higher risk of antihistamines for infants in general and for neonates and premature babies in particular, antihistamine treatment is contraindicated in breastfeeding mothers.

Contra-indicated in case
- hypersensitivity to cyproheptadine HCl and other drugs of similar chemical structure
- treatment with monoamine oxidase inhibitor (MAO)
- closed-angle glaucoma
- stenosing peptic ulcer
- symptomatic prostatic hypertrophy
- obstruction of the bladder neck
- pyloroduodenal obstruction
- in the elderly and weakened

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 may have cumulative effects with alcohol and other depressants CNS, for example hypnotics, sedatives, tranquillizers 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 must be determined and corrected if possible.
The intake of vitamins must accompany a complete diet, namely an absorption of protein and daily energy. No other vitamin, mineral or dietary supplement with or without vitamin A should be taken with this preparation unless under medical supervision

4.5. Interactions with other drugs and other forms of interactions
MAO inhibitors prolong and intensify anticholinergic effects of antihistamines. Antihistamines may have additive effects with alcohol and other central nervous

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

4.6. Pregnancy and breast feeding

Pregnancy Category B
Reproductive studies were conducted in rabbits, mice and rats with oral or subcutaneous doses up to 32 times the maximum oral dose recommended for humans. The results did not indicate any decrease in fertility or adverse effects on the fetus due to cyproheptadine HCL. HCl cyproheptadine was shown to be fetotoxic in rats when administered by intraperitoneal injection at doses four times higher than the maximum oral dose recommended 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 were observed in neonates. However, since studies in humans can not exclude the possibility of harm, cyproheptadine HCl should be used during pregnancy only when necessary.

BREASTFEEDING
It is currently impossible to know if this drug is excreted in human milk. Since many drugs are excreted in breast milk, and because of the risk of serious adverse reactions in infants who would be taking cyproheptadine HCl, decision to discontinue breastfeeding, or to discontinue the drug, taking into account the degree of need 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 disappear quickly with continued 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, tremor, irritability, insomnia, paresthesia, neuritis, convulsions, euphoria, hallucinations, hysteria and fainting.

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

Sensory disorders
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, hepatic 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
Dryness of the nose and throat, thickening of bronchial secretions, tightness of the chest, wheezing and nasal congestion.

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

The reporting of suspected side effects after approval of the drug is important. It allows continuous monitoring of the benefit / risk ratio of the drug.

4.9. Overdose

Antihistamine overdose reactions may 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 has not occurred 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 wash choice. Precautions against aspiration should be taken especially in infants and children.

For life-threatening CNS signs and symptoms, 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 into the intestine by osmosis and, therefore, are useful for their action in rapidly diluting 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 about overdose of vitamins 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 B_2 (Riboflavin)
Riboflavin is phosphorylated with 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 B_6 (Pyridoxine)
Pyridoxine, once absorbed, is rapidly converted into co-enzymes, pyridoxal phosphate and pyridoxamine phosphate, which play a vital role in protein metabolism. Seizures and hypochromic anemia have been observed in infants with pyridoxine deficiency.
Vitamin B_1 (Thiamine)
Thiamine (as co-enzyme, thiamine pyrophosphate) is associated with carbohydrate metabolism. Thiamine pyrophosphate also acts as a coenzyme 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 conversion to acetyl-coenzyme-A by a thiamine-dependent process. 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 the accumulation of lactate and pyruvate. Thiamine deficiency leads to fatigue, anorexia, gastrointestinal disorders, tachycardia, irritability and neurological symptoms. A large deficiency of thiamine (and other components of the vitamin B group) can cause beriberi disease.
VitamineB_3 (Niacin / Nicotinamide)
The biochemical functions of nicotinamide such as nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP) include degradation and synthesis of fatty acids, carbohydrates and amino acids as well as hydrogen transfer. Deficiency would produce pellagra and mental neurological changes.
Vitamin B_{12} (Cyanocobalamin)
Vitamin B12 is present in the body mainly as methylcobalamin, adenosylcobalamin and hydroxocobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine; In the isomerization of coenzyme methylmalonyl to coenzyme succinyl 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 oral dose of 4 mg cyproheptadine hydrochloride (labeled 14C) in tablet form in normal subjects, 2-20% of the radioactivity is excreted in the feces. Only about 34% of the radioactivity of the saddle is in unchanged form, which corresponds to less than 5.7% of the dose. At least 40% of the administered radioactivity is excreted in the urine. No amount of unchanged substance is detected in the urine of patients on daily doses continuously from 12 to 20 mg. The major metabolite found in human urine has been identified as a quaternary ammonium glucuronide conjugated with cyproheptadine hydrochloride. Elimination is decreased in case of renal failure.

Vitamin B2 (Riboflavin)

Riboflavin is absorbed by the gastrointestinal tract and into 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 B_6 (Pyridoxine)

Pyridoxine is absorbed by the gastrointestinal tract and converted to pyridoxal phosphate

active, which is related to plasma proteins. It is excreted in the urine as acid 4-pyriodoxic.

Vitamin B1 (Thiamine)

Thiamine is absorbed by the gastrointestinal tract and is widely distributed in most body tissues. Quantities exceeding the requirements of the organism are not stored but are excreted in the unchanged form of thiamine or its metabolites.

VitamineB3 (Niacin / Nicotinamide)

Nicotinic acid is absorbed from the gastrointestinal tract, is widely distributed in the body tissues, and has a short half-life.

Vitamin B12 (Cyanocobalamin)

Cyanocobalamin is absorbed by the gastrointestinal tract and is strongly bound to specific plasma proteins. A study with labeled vitamin B12 showed that it was rapidly taken up by the intestinal mucosa and maintained there for 2-3 hours. Maximum concentrations in blood and tissues occurred only 8 to 12 hours after dosing with peak concentrations in the liver within 24 hours. Cobalamines 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 DATA

6.1. List of excipients

Saccharose, Sodium Methyl Paraben, Sodium Propyl Paraben, Sorbitol 70%, Sodium Hydroxide, Bronpole, Glycerin, Citric Acid, Mixed Fruit Aroma 1038, Propylene Glycol

6.2. incompatibility

Not applicable

6.3. The duration of the conversation

24 months

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

6.5. Nature and contents of the pack
120 ml PET bottle with scoop

6.6. Special precautions for disposal and handling
Not applicable

7. HOLDER OF THE MARKETING AUTHORIZATION
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