LYSOVIT®
(B-Complex+Lysine)

1. NAME OF THE MEDICINAL PRODUCT

LYSOVIT®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

LYSOVIT® Syrup 120 ml

Description

Each 5 ml contains:

Thiamine HCl	4.16 mg
Riboflavin USP	1.66 mg
Pyridoxine HCl	1 mg
Niacinamide USP	18 mg
D-Panthenol USP	2.5 mg
Cyanocobalamin USP	8.33 mcg
Ascorbic Acid USP	75 mg
Inositol USP	5 mg
Lysine Monohydrochloride USP	33.33 mg

3. PHARMACEUTICAL FORM

Syrup

4. CLINICAL PARTICULARS

4.1. THERAPEUTIC INDICATIONS

1. For maintenance of health and to meet the extra energy needs of growing children.
2. Increases appetite and helps in recovery from illnesses.

4.2. POSOLOGY AND METHOD OF ADMINISTRATION

Children: 1 teaspoonful daily or as prescribed by the physician

Adults: One to two teaspoonsful daily.

Shake well before use.

Thiamine Benefits: Thiamine is recommended for digestive problems including poor appetite, ulcerative colitis, and ongoing diarrhea. People take thiamine for conditions related to low levels of thiamine (thiamine deficiency syndromes), including beriberi and inflammation of the nerves (neuritis) associated with pellagra or pregnancy.[4]

Thiamine - Daily Recommended Dietary Allowance (RDA): In adults, 1-2 mg of thiamine per day is commonly used.

Infants 0-6 months, 0.2 mg
Infants 7-12 months, 0.3 mg
Children 1-3 years, 0.5 mg
Children 4-8 years, 0.6 mg
Boys 9-13 years, 0.9 mg
Men 14 years and older, 1.2 mg[4]
Girls 9-13 years, 0.9 mg
Women 14-18 years, 1 mg
Women over 18 years, 1.1 mg
Pregnant women, 1.4 mg
Breast-feeding women, 1.5 mg

Riboflavin Benefits: Riboflavin had a direct impact on maintenance of good brain function. Riboflavin contains certain flavoproteins needed for the metabolism of essential fatty acids in the brain and for hormone regulation.[6] Riboflavin may help decrease the overall effects of depression by boosting mood and increasing energy levels. Riboflavin is one of the key components of the glutathione redox cycle, which is the process responsible for inhibiting lipid peroxidation and reperfusion oxidative injury.[7]

Riboflavin is probably effective for preventing migraine headaches and recommended for this purpose. It might help prevent the DNA damage caused by many carcinogens by acting as a coenzyme with several different cytochrome P450 enzymes.[8]

Riboflavin - Daily Recommended Dietary Allowance (RDA): The estimated average requirement and RDA for riboflavin that cover men and women between the ages of 19 and 70 y are 0.9–1.1 and 1.1–1.3 mg per day, respectively.

In Children (1-9 Years) 0.5 to 0.6 mg per day is recommended while in adolescents (10-18 years) - 0.9 to 1.3 mg per day is suggested.

Adequate Intakes of riboflavin for infants 0–12 months of age are based on mean volume (0.78 L/d) of milk consumed. Thus, Adequate Intake for infants 0–12 months is 0.3–0.4 mg per day.[5]

Pyridoxine Benefits: Pyridoxine has the ability to improve cardiovascular health. Along with folate and cobalamin, pyridoxine is said to help curb high levels of homocysteine in the heart. It has the potential to slow brain shrinkage. A study published in 2013, further supports this, saying that B vitamins also specifically slow down shrinkage in areas of the brain that are severely impacted by Alzheimer's disease.

Pyridoxine also has an effect on different mood disorders and neurological and psychiatric ailments. This is because they impact the methylation cycle directly. B vitamins are necessary for producing neurotransmitters and maintaining myelin — the fatty sheath that surrounds the nerve cells. It found that high doses of pyridoxine, inositol (vitamin B8) and cobalamin, taken in combination, helped improve schizophrenic symptoms.[12]

Pyridoxine - Daily Recommended Dietary Allowance (RDA): The ideal dose for pyridoxine supplementation depends on the condition. The typical adult dosage is 2.5 to 25 milligrams (mg) daily. After three weeks of supplementation, the dose should be lowered to just 1.5 to 2.5 mg per day.[13]

The recommended vitamin B6 amount for pregnant women is 1.9 milligrams (mg) per day, while breastfeeding mothers should get 2 mg per day of this vitamin from food.[14]

Niacin Benefits: Niacin is converted to NAD (nicotinamide adenine dinucleotide), NADH (nicotinamide adenine dinucleotide plus hydrogen), which serve necessary roles in oxidative respiration as electron carriers. NADP (nicotinamide adenine dinucleotide phosphate) and NADPH (nicotinamide adenine dinucleotide phosphate hydrogen) are also niacin-dependent biomolecules which are important in synthesis of nucleic acids, fatty acids, and cholesterol. Therefore, it plays an important role in DNA repair and production of steroid hormones.[19]

Niacin is well known to lower serum cholesterol; elevating good cholesterol HDL levels, lowering triglyceride levels, and somewhat lessening bad cholesterol LDL levels. It also prevents cardiovascular risks such as atherosclerosis (hardening of the arteries), and possibly even prevention of a second heart attack for those that have already had one heart attack.[20]

Niacin - Daily Recommended Dietary Allowance (RDA): The recommended dietary allowance (RDA) for niacin is based on the prevention of deficiency. Pellagra can be prevented by about 11 mg NE/day, but 12 mg to 16 mg NE/day has been found to normalize the urinary excretion of niacin metabolites (breakdown products) in healthy young adults.

For infants, 0 to 6 months; 2 mg NE/day and for 7 to 12 months; 4 mg NE/day of Niacin is recommended.

For Children, 1 to 3 years: 6 mg NE/day; 4 to 8 years: 8 mg NE/day; 9 to 13 years: 12 mg NE/day of Niacin is recommended.

For Adolescents (male), 16 mg NE/day while for females 14 mg NE/day is recommended.
18 mg NE/day is suggested for pregnant and 17 mg NE/day for breast feeding females.[21]

(*NE, niacin equivalent: 1 mg NE = 60 mg of tryptophan = 1 mg niacin)

Pantothenic Acid Benefits: Vitamin B5 has stimulating properties that help regulate the release of hormones from different glands in the body and ensures they are balanced and performing their needed tasks. It helps retain good fats and remove excessive fats from the body, which keeps the blood vessels cholesterol free.

Vitamin B5 is essential for the metabolic processes in the body; it helps the body break down fats and complex carbohydrates to energize the body. The release of energy from the fast metabolic process helps keep the body and mind functioning properly and reduces any signs of fatigue. It also helps the body generate more hemoglobin by acting in cohesion with elements such as iron and copper.

A few studies show that people suffering from rheumatoid arthritis all show a deficiency in vitamin B5. Adding b5 to your diet can actually help calm the inflammation caused by this kind of arthritis and also reduce the pain.[24]

Pantothenic Acid - Daily Recommended Dietary Allowance (RDA): Average daily level of intake sufficient to meet the nutrient requirements of nearly all (97%–98%) healthy individuals; often used to plan nutritionally adequate diets for individuals.[25]

Age	Male	Female	Pregnancy	Lactation
Birth to 6 months	1.7 mg	1.7 mg		
7–12 months	1.8 mg	1.8 mg		
1–3 years	2 mg	2 mg		
4–8 years	3 mg	3 mg		
9–13 years	4 mg	4 mg		
14–18 years	5 mg	5 mg	6 mg	7 mg
19+ years	5 mg	5 mg	6 mg	7 mg

Cyanocobalamin Benefits: Vitamin B-12 is crucial to the normal function of the brain and the nervous system. It is also involved in the formation of red blood cells and helps to create and regulate DNA.

The metabolism of every cell in the body depends on vitamin B-12, as it plays a part in the synthesis of fatty acids and energy production. Vitamin B-12 enables the release of energy by helping the human body absorb folic acid.

The human body produces millions of red blood cells every minute. These cells cannot multiply properly without vitamin B-12. The production of red blood cells reduces if vitamin B-12 levels are too low. Anemia can occur if the red blood cell count drops.[28]

Cyanocobalamin - Daily Recommended Dietary Allowance (RDA): In the U.S., the National Institutes of Health (NIH) recommend that teens and adults over the age of 14 years should consume 2.4 micrograms

(mcg) of vitamin B-12 a day. Pregnant women should be sure to consume 2.6 mcg, and lactating women 2.8 mcg.

Excessive intake of vitamin B-12 has not demonstrated toxic or harmful qualities.[28]

Vitamin C Benefits: Ascorbic acid plays an important role in the maintenance of collagen which represents about one third of the total body protein.[30] There is considerable evidence that vitamin C protects against respiratory tract infections and reduces risk for cardiovascular disease and some cancers.[31]

It is essential for wound healing, and facilitates recovery from burns. Play role in collagen, carnitine, hormone and amino acid production. It is an antioxidant and supports immune function, and facilitates the absorption of iron.[35]

Vitamin C - Daily Recommended Dietary Allowance (RDA): Intake recommendations for vitamin C and other nutrients are provided in the Dietary Reference Intakes (DRIs) developed by the Food and Nutrition Board (FNB) at the Institute of Medicine (IOM) of the National Academies (formerly National Academy of Sciences).[32]

Age	Male	Female	Pregnancy	Lactation
0–6 months	40 mg*	40 mg*		
7–12 months	50 mg*	50 mg*		
1–3 years	15 mg	15 mg		
4–8 years	25 mg	25 mg		
9–13 years	45 mg	45 mg		
14–18 years	75 mg	65 mg	80 mg	115 mg
19+ years	90 mg	75 mg	85 mg	120 mg
Smokers	Individuals who smoke require 35 mg/day more vitamin C than non-smokers.			

* Adequate Intake (AI)

Lysine - Daily Recommended Dietary Allowance (RDA): Normal requirement of lysine have been found to be about 8 g per day or 12 mg/kg in adults. Children and infant need more, 44 mg/kg per day for 11 to 12 years old, and 97 mg/kg per day for 3 to 6 months old. Lysine is highly concentrated in muscle compared to other amino acids. High in food such as wheat germ, cottage cheese and chicken.

Lysine inhibits transport of L-arginine, depletes intra-cellular stores of L-arginine, and reduces NO production. Studies have been done to investigate L-lysine treatment as a potential new add-on

treatment for patients with schizophrenia, and as a novel means of targeting the NO pathway in order to treat a psychiatric disorder.[39]

4.3. CONTRAINDICATIONS

No Information available

4.4. SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Thiamine: Thiamine is LIKELY SAFE for pregnant or breast-feeding women when taken in the recommended amount of 1.4 mg daily. Not enough is known about the safety of using larger amounts during pregnancy or breast-feeding.

People that are critically ill such as those that had surgery might have low levels of thiamine. These people might require thiamine supplements.

People undergoing hemodialysis treatments might have low levels of thiamine. They might require thiamine supplements.[4]

Riboflavin (vitamin B2): Avoid use of large dose of riboflavin because it may result in bright yellow discoloration of the urine, which may interfere with certain lab tests.[9]

Pyridoxine (Vitamin B6): It is not recommended for the population allergic to pyridoxine. During pregnancy, this vitamin has been found to be safe when used in recommended doses. This vitamin passes into breast milk and is considered to be safe during breast-feeding when used in recommended doses.[15]

Niacin: Niacin is recommended to use cautiously in people with liver or kidney problems, because it can cause or worsen liver damage.

Niacin is LIKELY SAFE for pregnant and breast-feeding women when taken in the recommended amounts. It must be started at a low dose and increased gradually, in order to avoid intolerable flushing.

Niacin might worsen allergies by causing histamine, the chemical responsible for allergic symptoms, to be released.[22]

Pantothenic acid: Pantothenic acid is LIKELY SAFE in pregnancy and lactation, when taken by mouth in recommended amounts of 6 mg per day during pregnancy and 7 mg per day during breast-feeding. Avoid using larger amounts of pantothenic acid.[26]

Cyanocobalamin: Not suitable for people hypersensitive to Cyanocobalamin. It is recommended to use Vitamin B12 with caution in patients with Leber optic nerve atrophy.[29]

Vitamin C: It is LIKELY SAFE for pregnant or breast-feeding women when taken by mouth in amounts no greater than 2000 mg daily for women over 19 years-old, and 1800 mg daily for women 14 to 18 years-old, or when given intravenously (by IV) or intramuscularly and appropriately.[33]

Lysine: Not recommended for people who are allergic to Lysine. Taking calcium along with lysine can increase the amount of calcium in the body.
It is suggested to avoid during pregnancy and lactation.
Used with caution in people with kidney disease.[34]

4.5. INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Taking calcium along with lysine can increase the amount of calcium in the body.

4.6. FERTILITY, PREGNANCY AND LACTATION

Thiamine: Thiamine is LIKELY SAFE for pregnant or breast-feeding women when taken in the recommended amount of 1.4 mg daily. Not enough is known about the safety of using larger amounts during pregnancy or breast-feeding.

Pyridoxine (Vitamin B6): During pregnancy, this vitamin has been found to be safe when used in recommended doses. This vitamin passes into breast milk and is considered to be safe during breast-feeding when used in recommended doses.[15]

Niacin: Niacin is LIKELY SAFE for pregnant and breast-feeding women when taken in the recommended amounts. It must be started at a low dose and increased gradually, in order to avoid intolerable flushing.

Pantothenic acid: Pantothenic acid is LIKELY SAFE in pregnancy and lactation, when taken by mouth in recommended amounts of 6 mg per day during pregnancy and 7 mg per day during breast-feeding. Avoid using larger amounts of pantothenic acid.[26]

Vitamin C: It is LIKELY SAFE for pregnant or breast-feeding women when taken by mouth in amounts no greater than 2000 mg daily for women over 19 years-old, and 1800 mg daily for women 14 to 18 years-old, or when given intravenously (by IV) or intramuscularly and appropriately.[33]

Lysine: It is suggested to avoid during pregnancy and lactation.

4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No Information available

4.8. UNDESIRABLE EFFECTS[35]

NIACIN TOXICITY: Niacin in large amounts is sometimes used to lower low-density lipoprotein (LDL) cholesterol and triglyceride levels and to increase high-density lipoprotein (HDL) cholesterol levels. Symptoms may include flushing and, rarely, hepatotoxicity.

VITAMIN B_6 TOXICITY: The ingestion of megadoses (>500 mg/day) of pyridoxine (e.g., taken to treat carpal tunnel syndrome or premenstrual syndrome although efficacy is unproved) may cause peripheral neuropathy with deficits in a stocking-glove distribution, including progressive sensory ataxia and severe impairment of position and vibration senses. Senses of touch, temperature, and pain are less affected. Motor and central nervous systems are usually intact. Diagnosis is clinical. Treatment is to stop taking vitamin B_6. Recovery is slow and, for some patients, incomplete.

VITAMIN C TOXICITY: The upper limit for vitamin C intake is 2000 mg/day. Up to 10 g/day of vitamin C are sometimes taken for unproven health benefits, such as preventing or shortening the duration of viral infections or slowing or reversing the progression of cancer or atherosclerosis. Such doses may acidify the urine, cause nausea and diarrhea, interfere with the healthy antioxidant-pro oxidant balance in the body, and, in patients with thalassemia or hemochromatosis, promote iron overload. Intake below the upper limit does not have toxic effects in healthy adults.

4.9. OVERDOSE

Thiamine, Riboflavin and Folate are essentially nontoxic.

In case of any side effects, see your Healthcare professional.

5. PHARMACOLOGICAL PROPERTIES

5.1. PHARMACODYNAMIC PROPERTIES

Thiamine: is a water soluble vitamin is one of the eight essential B vitamins that help the body convert food (carbohydrates, fat, and protein) into energy. These vitamins are vital for proper functioning of the central and peripheral nervous system. The human body does not produce endogenous thiamine; therefore, it must be ingested.[1]

It is involved in carbohydrate, fat, amino acid, glucose, and alcohol metabolism and is essentially nontoxic.[35]

Occurrence in Foods: In most animal tissues, over 90% of the thiamin occurs in TMP*, TDP**, and TTP***. The predominant form (80–85%) is TDP, the active coenzyme form. The most abundant form in plant tissues is free thiamine.

*TMP; Thiamine Monophosphate
**TDP; Thiamine Diphosphate
***TTP; Thiamine Triphosphate

It is usually available in such foods as fortified breads, cereals, pasta, whole grains, lean meats, fish, dried beans, peas and soybeans.[2]
Practically no thiamin is contained in high-fat products (e.g., vegetable oil) and refined products (e.g., sugar). The large content of thiamine is present in Yeast, sunflower seeds, flour.[3]

Riboflavin (vitamin B_2)**:** was first isolated from milk as the water-soluble, yellowish pigment called lactochrome. It is involved in carbohydrate metabolism as an essential coenzyme in many oxidation-reduction reactions. Activation of riboflavin into its physiologically important coenzymes requires an initial phosphorylation by flavokinase (ATP: riboflavin 5-phosphotransferase) to form FMN (Flavin mononucleotide) and a subsequent pyrophosphorylation with AMP catalyzed by FAD (Flavin Adenine Dinucleotide) synthetase (ATP: FMN adenylyl transferase).[5]

Occurrence in Food: Primary dietary forms of riboflavin from natural sources are FMN (Flavin mononucleotide) and FAD (Flavin adenine dinucleotide). Rich sources of total riboflavin include plant foods as well as animal sources, namely organ meats, poultry, fish, and eggs; dairy products (milk and cheese) offer a rich source of the parent compound, riboflavin, which contributes significantly to the RDA for children and adult populations.
High quality, protein-rich foods are excellent sources not only of riboflavin but B vitamins in general. Flavoenzymes catalyze a diverse number of reactions that interact metabolically with other B vitamin–dependent enzymes present in plant and animal food sources.[5]

Pyridoxine (Vitamin B_6)**:** Pyridoxine is a water-soluble vitamin (meaning it cannot be stored in the body) that is essential in different body processes. It includes a group of closely related compounds: pyridoxine, pyridoxal, and pyridoxamine.

Vitamin B6 is important in heme and nucleic acid biosynthesis and in lipid, carbohydrate, and amino acid metabolism.[35]

Occurrence in Food: Pyridoxine is available in various foods, which is why there's less risk of being deficient in it, compared to other vitamins. Some of the best sources of vitamin B6 are: Poultry, such as turkey and chicken, fish including wild-caught salmon, beef liver and other organ meat, Bell pepper, Starchy vegetables like Baked potatoes, nuts like cashews and hazelnuts, as well as sunflower seeds.[11]

Niacin (nicotinic acid, nicotinamide, niacinamide)**:** Niacin is one of the several water-soluble vitamins your body needs to survive. It is a coenzyme, like thiamine and riboflavin that is responsible for energy release from carbohydrates.[16]

Its derivatives include nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP), which are coenzymes in oxidation-reduction reactions. They are vital in cell metabolism. Because dietary tryptophan can be metabolized to niacin, foods rich in tryptophan (e.g., dairy products) can compensate for inadequate dietary niacin.[35]

Occurrence in Food: Several starchy vegetables provide a source of niacin. Eating one baked potato boosts your niacin intake by 2.2 milligrams, and sweet potatoes provide 2.2 milligrams of niacin per potato.[17]

Other sources of Niacin includes: Beef and lamb meat, liver, kidney, chicken, cheese and beans, leafy vegetables, mushrooms, yeast extract, nuts and sunflower seeds, whole wheat bread, enriched pasta. Some foods such as breakfast cereals are rich in niacin.[18]

Pantothenic acid: Also known as Pantothenate or Vitamin B5 is a pantoic acid linked with β-alanine through an amide bond. Pantothenic acid is of biologic importance because of its incorporation into coenzyme A (CoA) and Acyl Carrier Protein (ACP), on which acetylation and acylation, respectively, and other interactions depend.
Coenzyme A is an indispensable cofactor in all living organisms, where it functions in over 70 enzymatic pathways. Most bacteria, plants, and fungi synthesizes pantothenic acid; thus, the vitamin is found virtually everywhere in nature.[23]

Occurrence in Food: Pantothenic acid is found in both free and conjugate form in virtually all plant and animal cells.

Chicken, beef, potatoes, oats, tomato products, liver, kidney, peanuts, almonds, yeast, egg yolk, broccoli, cheese, lobster, and whole grains are reported to be the major sources of pantothenic acid. Others such as meats, vegetables, milk, and fruits also contain moderate amounts of pantothenic acid.[23]

Cyanocobalamin (Folate): Vitamin B12 also known as cobalamin comprises a number of forms including cyano-, methyl-, deoxyadenosyl- and hydroxy-cobalamin. The cyano form, which is used in supplements, is found in trace amounts in food. The other forms of cobalamin can be converted to the methyl- or 5-deoxyadenosyl forms that are required as co factors for methionine synthase and L-methyl-malonyl-CoA mutase.

Occurrence in Food: Vitamin B12 is synthesized by certain bacteria in the gastrointestinal tract of animals and is then absorbed by the host animal. Vitamin B12 is concentrated in animal tissues, hence, vitamin B12 is found only in foods of animal origin. It does not typically occur in plant foods.[27]

A good dietary source of Vitamin B12 includes; Beef, poultry, lamb, fish (especially haddock and Tuna), dairy products (milk, cheese, yoghurt), some nutritional yeast products, eggs.

Some types of soya milk and breakfast cereals are fortified with vitamin B-12.[28]

Vitamin C: Ascorbic acid is one of the important water soluble vitamins. It is essential for collagen, carnitine and neurotransmitters biosynthesis. Most plants and animals synthesize ascorbic acid for their own requirement. However, humans cannot synthesize ascorbic acid due to lack of an enzyme gulonolactone oxidase. Hence, ascorbic acid has to be supplemented mainly through fruits, vegetables and tablets.

The major metabolites of ascorbic acid in human are dehydroascorbic acid, 2, 3-diketogulonic acid and oxalic acid.[30]

Occurrence in Food: Ascorbic acid is widely distributed in fresh fruits and vegetables. It is present in fruits like orange, lemons, grapefruit, watermelon, papaya, strawberries, cantaloupe, mango,

pineapple, raspberries and cherries. It is also found in green leafy vegetables, tomatoes, broccoli, green and red peppers, cauliflower and cabbage.

Most of the plants and animals synthesize ascorbic acid from D-glucose or D-galactose. A majority of animals produce relatively high levels of ascorbic acid from glucose in liver.

L-ascorbic acid and its fatty acid esters are used as food additives, antioxidants, browning inhibitors, reducing agents, flavor stabilizers, dough modifiers and color stabilizers.[30]

Inositol: Inositol (isomer of glucose), a naturally occurring substance found in whole grain cereals, fruits and plants in which it occur as hexaphosphate, phytic acid. It also occurs in vegetables and meat in other forms. Inositol is physiologically involved in lipid metabolism and also been investigated in the treatment of depression and anxiety, diabetic neuropathy, neonatal respiratory distress syndrome and retinopathy of prematurity.[36]

Inositol 1,4,5-trisphosphate 3-kinase (IP3 3-kinase/IP3K) plays an important role in signal transduction in animal cells by phosphorylating inositol 1,4,5-trisphosphate (IP3) to inositol 1,3,4,5-tetrakisphosphate (IP4). Both IP3 and IP4 are critical second messengers which regulate calcium (Ca^{2+}) homeostasis.[38]

Studies have demonstrated that myoinositol and D-Chiro-inositol can reduce insulin resistance, improve ovarian function and reduce androgen levels in women with PCOs. The effect of myoinositol on ovarian function and oocyte quality is independent of its concentration in circulation.[37]

Lysine: It is one of nine essential amino acids in human required for growth and tissue repair, supplied by many foods, specially red meat, fish, and dairy products. Lysine seems to be active against herpes simplex viruses and present in many forms of diet supplements.

Normal Lysine metabolism is dependent upon nutrients including niacin, vitamin B6, riboflavin, vitamin C, glutamic acid and iron. Although high protein diet results in loss of large amount of calcium in urine, so does lysine deficiency. Lysine use as an adjunct therapy because it reduce calcium loss in urine. Lysine deficiency may also result in immunodeficiency.[39]

5.2. PHARMACOKINETIC PROPERTIES

Pyridoxine is metabolized in the body to pyridoxal phosphate, which is a coenzyme for synthesis of amino acids, neurotransmitters (serotonin, norepinephrine), sphingolipids, aminolevulinic acid[10] and involved in many important reactions in blood, CNS, and skin metabolism.[35]

Vitamin B12 is bound to protein in food and is available for absorption after it has been cleaved from protein by the hydrochloric acid produced by the gastric mucosa.

5.3. PRECLINICAL SAFETY DATA

No Information available.

6. PHARMACEUTICAL PARTICULARS

6.1. LIST OF EXCIPIENTS

Sugar granulated USP
Methyl paraben
Sodium benzoate
Potassium sorbate
Sodium saccharine granular
Glucose liquid USP
Glycerine

L-lysine mono hydrochloride
Thiamine hcl
Pyridoxine hcl
Niacinamide
Riboflavin 5'po4 sodium
Cyanocobalamine
Inositol
Sodium EDTA
Ascorbic acid
Sodium ascorbate
Citric acid
Veltol
D-panthenol
Blood orange essence
Cosmo artificial quince
Purified Water

6.2. INCOMPATIBILITIES

Information not available.

6.3. SHELF LIFE

15 months

6.4. SPECIAL PRECAUTIONS FOR STORAGE

Replace cap securely after use.

Avoid Exposure from heat and sunlight. Keep at room temperature. Keep all medications out of the reach of children. In case of overdose of medicine, contact your doctor/hospital immediately.

6.5.HOW SUPPLIED

Syrup 120 ml

Lysovit/LPD/PK-02

Manufactured by:
Pfizer Pakistan Limited.
B-2, S.I.T.E. Karachi.

7. REFERENCES

1. *Thiamine Deficiency and Delirium.* **Kenneth Osiezagha, Shahid Ali et.al.** 4, s.l. : PMC-NCBI, 2013, Vol. 10.

2. Vitamin B1 Monograph. *Clarocet.* [Online] Feb 2015. [Cited: July 28, 2018.] http://www.clarocet.com/vitamin-b1/.

3. *THIAMIN | Properties and Determination.* **Y.EgiT.Kawasaki.** s.l. : Science Direct, 2003, Encyclopedia of Food Sciences and Nutrition (Second Edition), pp. 5767-5772.

4. Thiamine (Vitamin B1). *Rx List.* [Online] [Cited: July 28, 2018.] https://www.rxlist.com/thiamine_vitamin_b1/supplements.htm#HowDoesItWork.

5. *Riboflavin.* **Pinto, John T.** 5, s.l. : PMC, Sept 2016, Adv Nutr., Vol. 7.

6. *B Vitamins and the Brain: Mechanisms, Dose and Efficacy—A Review.* **Kennedy, David O.** 2, s.l. : PMC, NCBI, Feb 2016, Nutrients., Vol. 8, p. 68.

7. *Riboflavin (vitamin B_2) and oxidative stress: a review.* **Ashoori M, Saedisomeolia A.** 11, s.l. : PMC, NCBI, 2014, Vol. 111, pp. 1985-91.

8. Riboflavin. *NIH (National Institute of Health) Office of Dietary Supplements.* [Online] March Updated 2018. [Cited: July 29, 2018.] https://ods.od.nih.gov/factsheets/Riboflavin-HealthProfessional/.

9. Drug Information System. *Riboflavin (Vitamin B2).* [Online] [Cited: July 29, 2018.] http://www.druginfosys.com/drug.aspx?drugcode=648&type=1.

10. PubChem - Open Chemistry Database. *Pyridoxine.* [Online] [Cited: July 29, 2018.] https://pubchem.ncbi.nlm.nih.gov/compound/pyridoxine#section=Top.

11. **Editor, Fitday.** 9 Foods Rich in Vitamin B6. *FitDay.* [Online] [Cited: July 29, 2018.] https://www.fitday.com/fitness-articles/nutrition/vitamins-minerals/9-foods-rich-in-vitamin-b6.html.

12. All About Pyridoxine: Vitamin B6 Facts You Should Know. *Mercola.Com - Take Control of Your Health.* [Online] [Cited: July 29, 2018.] https://articles.mercola.com/vitamins-supplements/pyridoxine.aspx.

13. pyridoxine (vitamin B6) . *EMedicine Health.* [Online] Updated March 2011. [Cited: July 29, 2018.] https://www.emedicinehealth.com/drug-pyridoxine_vitamin_b6/article_em.htm.

14. Vitamin B6 In Your Pregnancy Diet. *Baby Center.* [Online] Updated July 2016. [Cited: July 29, 2018.] https://www.babycenter.com/0_vitamin-b6-in-your-pregnancy-diet_666.bc.

15. pyridoxine - oral, Neuro-K, Vitamin B-6. *MedcineNet.com.* [Online] Revised March 2013. [Cited: July 29, 2018.] https://www.medicinenet.com/pyridoxine-oral/article.htm.

16. *Vitamin and Mineral Basics: The ABCs of Healthy Foods and Beverages, Including Phytonutrients and Functional Foods.* **MS, Jacqueline B. Marcus.** s.l. : Science Direct, 2013, Culinary Nutrition, pp. 279-331.

17. **Tremblay, Sylvie.** *Fruits & Vegtables That Are a Good Source for Niacin.* s.l. : Healthy Eating-Nutrition, 2018.

18. **Nordqvist, Christian.** *Why do we need vitamin B-3, or niacin?* s.l. : Medical News Today, 2016.

19. **Jasvinder Chawla, David Kvarnberg.** Neurologic Aspects of Systemic Disease Part II. s.l. : Handbook of clinical Neurology, 2014.

20. **Gilkes, Madeline.** Health Benefits of Niacin (Vitamin B3) In The Diet. *Ausmed.* [Online] August 2014. [Cited: July 30, 2018.] https://www.ausmed.com/articles/health-benefits-niacin-vitamin-b3/.

21. *Niacin.* **Mirella Meyer-Ficca, James B Kirkland.** 3, May 2016, Advances In Nutrition, Vol. 7, pp. 556–558.

22. NIACIN AND NIACINAMIDE (VITAMIN B3). *Rx List.* [Online] [Cited: July 30, 2018.] https://www.rxlist.com/niacin_and_niacinamide_vitamin_b3/supplements.htm.

23. *PANTOTHENIC ACID: AN OVERVIEW FOCUSED ON MEDICAL ASPECTS.* **Antonio Sampedro, Javier Rodriguez-Granger et.al.** 21, July 2015, European Scientific Journal, Vol. 11, pp. 1-18.

24. **James, Kayla.** 11 Benefits of Vitamin B5 (Pantothenic Acid). *Natural Food Series.* [Online] May 2018. [Cited: July 30, 2018.] https://www.naturalfoodseries.com/11-benefits-vitamin-b5-pantothenic-acid/.

25. National Institute of Health. *U.S Department of Health & Human Services.* [Online] Updated June 2018. [Cited: July 30, 2018.] https://ods.od.nih.gov/factsheets/PantothenicAcid-HealthProfessional/.

26. Pantothenic Acid (Vitamin B5). *Emedicine Health.* [Online] [Cited: July 30, 2018.] https://www.emedicinehealth.com/pantothenic_acid_vitamin_b5-page2/vitamins-supplements.htm.

27. *Vitamin B12 in Health and Disease.* **Samman, Fiona O'Leary and Samir.** 3, s.l. : NCBI, March 2010, Nutrients. , Vol. 2, pp. 299-316.

28. **Nordqvist, Christian.** Everything you need to know about vitamin B-12. *Medical News Today.* [Online] November 28, 2017. [Cited: August 1, 2018.] https://www.medicalnewstoday.com/articles/219822.php.

29. **John P. Cunha, DO, FACOEP.** CYANOCOBALAMIN. *Rx List.* [Online] Reviewed on May 18, 2017. [Cited: August 1, 2018.] https://www.rxlist.com/consumer_cyanocobalamin_vitamin_b12/drugs-condition.htm.

30. *Vitamin C in human health and disease is still a mystery? An overview.* **Naidu, K Akhilender.** 7, 2003, Nutrition Journal, Vol. 2.

31. *Vitamin C: Overview & Update.* **Amanda K. Schlueter, Carol S. Johnston.** 1, March 9, 2011, Vol. 16, pp. 49-57.

32. Institute of Medicine. Food and Nutrition Board. . *Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids.* [Online] 2000. [Cited: August 2, 2018.] https://ods.od.nih.gov/factsheets/VitaminC-HealthProfessional/#en8.

33. Vitamin C (Ascorbic Acid). *WebMD.* [Online] [Cited: August 2, 2018.] https://www.webmd.com/vitamins/ai/ ingredientmono-1001/ vitamin-c-ascorbic-acid.

34. **John P. Cunha, DO, FACOEP.** Lysine. *Rx List.* [Online] Revised May 15, 2017. [Cited: August 2, 2018.] https://www.rxlist.com/consumer_lysine/drugs-condition.htm.

35. Merck Manual for Professionals. Last full review/revision October 2014 by Larry E. Johnson, MD, PhD. Content last modified October 2014

36. IBM Microemedex, Pharmaceuticals Knowledge. Inositol-Profile Accessed on 16-July-2018. http://www.micromedexsolutions.com/micromedex2/librarian/CS/0A3214/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/49A1D4/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.IntermediateToDocumentLink?docId=7877-p&contentSetId=30&title=Inositol&servicesTitle=Inositol

37. Karla, et.al, The Inositol & Polycystic ovary syndrome. Indian J Endocrinol Metab. 2016 Sep-Oct; 20(5): 720–724. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5040057/

38. Cell Research (2005) 15, 83–91. doi:10.1038/sj.cr.7290270

39. NIH, U.S National Library of Medicine. Lysine (Compound Summary for CID 5962), Accessed on 16-July-2018. Available at; https://pubchem.ncbi.nlm.nih.gov/compound/L-lysine#section=Top