

For the use of Registered Medical Practitioner Only
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1. Generic Name and Brand Name

Lysine, Zinc and Multivitamins Syrup
Betonin® KIDS

2. Qualitative and Quantitative composition

Each 15ml (1 tablespoonful approx.) contains:

Nicotinamide I.P. 45mg
Pyridoxine Hydrochloride I.P. 1.5mg
Cyanocobalamin I.P. 5 mcg
Zinc (as Zinc Sulphate I.P.) 10 mg
Lysine Hydrochloride I.P. 100mg
Non Syrupy base q.s.

Colour: Carmoisine

Appropriate overages of Vitamins added to compensate loss on storage.

3. Dosage form and strength

Refer section 1 & 2

4. Clinical Particulars**4.1. Therapeutic Indication**

Therapeutic use in children with vitamin B-complex deficiency.

In conditions where vitamin B complex supplementation is required including anorexia, prolonged diarrhea and other disorders of the digestive system, adjuvant therapy with broad spectrum antibiotics and dietary deficiencies.

4.2. Posology and method of administration

Children - 5ml twice daily or as directed by the physician.

4.3. Contraindications

Contraindicated in patients known to be hypersensitive to any of its constituents.

4.4. Special warnings and precautions for use

- Keep out of reach of children.
- Do not give for prolonged periods in doses higher than those recommended.
- To be used as per the recommended dose and duration.
- Avoid taking large amounts of calcium and lysine at the same time

4.5. Drugs interactions

Sr. No.	Drug	Drug interactions	Remarks
1.	Phenytoin	Effect with pyridoxine Co- administration decreases the effectiveness of phenytoin and increase the possibility of seizures.	Do not administer large doses of pyridoxine (vitamin B6) along with phenytoin

Sr. No.	Drug	Drug interactions	Remarks
2.	Amiodarone	Effect with pyridoxine Co administration increases the chances of sunburn, blistering, or rashes on areas of skin exposed to sunlight.	Wear the sunblock and protective clothing
3.	Phenobarbital	Effect with pyridoxine Co- administration decreases the effectiveness of Phenobarbital and increases the possibility of seizure	Do not administer large doses of pyridoxine (vitamin B6) along with Phenobarbital
4.	Levodopa	Effect with pyridoxine Co- administration decreases the effectiveness of Levodopa	Do not administer pyridoxine (vitamin B6) along with Levodopa
5.	Chloramphenicol	Effect with vitamin B12 Co- administration decreases the effects of vitamin B12 on new blood cell	Monitor the blood cells levels with CBC report
6.	Bishydroxycoumarin.	Co- administration influences the intensity and duration of action of bishydroxycoumarin.	--
7.	H2 Blockers (cimetidine, famotidine, nizatidine, ranitidine)	Use of H2 blockers may suppress the absorption of Vitamin B12	--
8.	Tetracycline Antibacterials	Zinc may reduce the absorption of concurrently administered tetracyclines, also the absorption of zinc may be reduced by tetracyclines	When both are being given an interval of at least three hours should be allowed.
9.	Quinolone Antibacterials	Zinc may reduce the absorption of quinolones; ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin.	Concurrent administration should be avoided

Sr. No.	Drug	Drug interactions	Remarks
10.	Calcium	Concomitant use of calcium supplements with lysine may be associated with increased absorption and reduced elimination of calcium.	--
11.	Aminoglycosides	Increased toxicity may occur in patients taking lysine	--

4.6. Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy and lactation:

Not applicable

Pediatric patients:

The safety has not been established in children below 2 years of age. Not recommended for use in children below 2 years.

4.7. Effects on ability to drive and use machines

Not applicable

4.8. Undesirable effects

At the recommended dosage, side effects are unlikely to occur. Gastrointestinal adverse reactions, such as diarrhea, nausea, and abdominal pain, have been reported with lysine ingestion. Zinc salts may cause abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation and gastritis. There have also been cases of irritability, headache and lethargy observed.

4.9. Overdose

There are no known reports of overdose with this syrup.

There is no specific antidote to it. Treatment includes symptomatic treatment as directed by the physician.

5. Pharmacological properties

5.1. Mechanism of action

Lysine is an essential amino acid in human nutrition that can only be obtained through diet or supplementation. Amino acids, including lysine, are fundamental constituents of all proteins. They promote protein production, reduce catabolism, promote wound healing,

and act as buffers in extracellular and intracellular fluids. Lysine improves calcium assimilation.

Pyridoxine or vitamin B6 helps in the proper functioning of sugars, fats, and proteins in the body. At the same time, it maintains the proper growth and development of the brain, nerves, skin, and many other parts of the body.

Cyanocobalamin or Vitamin B12 is required for the proper function and development of the brain, nerves, blood cells, and many other parts of the body.

Nicotinamide is incorporated into nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP). NAD and NADP are coenzymes in a wide variety of enzymatic oxidation-reduction reactions essential for tissue respiration, lipid metabolism, and glycogenolysis.

5.2. Pharmacodynamic properties

Lysine: Amino acids, including lysine, are fundamental constituents of all proteins. They promote protein production, reduce catabolism, promote wound healing, and act as buffers in extracellular and intracellular fluids. Lysine improves calcium assimilation.

Zinc sulphate: Zinc is an essential trace element involved in many enzyme systems. Severe deficiency causes skin lesion, alopecia, diarrhoea, increased susceptibility to infections and failure to thrive in children. Symptoms of less severe deficiency include distorted or absent perceptions of taste and smell and poor wound healing.

Pyridoxine or vitamin B6 helps in the proper functioning of sugars, fats, and proteins in the body. At the same time it maintains the proper growth and development of the brain, nerves, skin, and many other parts of the body.

Cyanocobalamin or Vitamin B12 is required for the proper function and development of the brain, nerves, blood cells, and many other parts of the body. Vitamin B12 is present in the body mainly as methylcobalamin and as adenosyl cobalamin and hydroxocobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine; in the isomerization of methylmalonyl co-enzyme to succinyl co-enzyme and with folate in several metabolic pathways respectively. Deficiency of Vitamin B12 interferes with haemopoiesis and produces megaloblastic anaemia.

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5.3. Pharmacokinetic properties

Absorption:

Lysine: Lysine is absorbed well after oral route. Later, it is transported to the liver from the gut via portal circulation for metabolism. Lysine is rapidly transported to muscle tissue, and within 5 to 7 hours following ingestion is highly concentrated in the muscle.

Zinc: Absorption by two mechanisms: Carrier mediated and passive mechanism. Excretion is entirely through feces. Zinc is absorbed from the gastrointestinal tract and distributed throughout the body.

Vitamin B Complex (Vitamin B6 and B12): They are absorbed by active transport process. They are rapidly eliminated and not stored in the body. Vitamins B complex containing Nicotinamide, pyridoxine and cyanocobalamin are well absorbed from the gastro-intestinal tract.

Distribution:

The components are widely distributed to all tissues in the body.

Metabolism and elimination:

Lysine is metabolized in liver. Its metabolism involves protein synthesis and oxidative catabolism. Lysine catabolism occurs almost exclusively in the liver. It does not undergo transamination.

Zinc: The highest concentrations occur in hair, eyes, male reproductive organs and bone. Lower levels are present in liver, kidney and muscle. In blood 80% is found in erythrocytes. Plasma zinc levels range from 70 to 110µg/dL and about 50% of this is loosely bound to albumin. About 7% is amino-acid bound and the rest is tightly bound to alpha 2-macroglobulins and other proteins.

Pyridoxine hydrochloride (Vitamin B6)

The half life of pyridoxine ranges from 15-20 days. Once absorbed vitamin B6 is converted to its active co-enzyme from pyridoxal 5-phosphate. Muscle is the major storage site for pyridoxal 5-phosphate. It is degraded in the liver to 4- pyridoxic acid which is eliminated by the kidneys.

Nicotinamide

Nicotinamide is readily taken up into tissues and utilised for the synthesis of the coenzyme forms nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP). Nicotinamide is degraded in the liver and other organs to a number of products that are excreted in the urine, the major metabolites being N-methyl-2-pyridone-5-carboxamide and n-methylnicotinamide.

Pharmacokinetics in Renal Impairment:

There have been no specific studies in renal impairment.

Pharmacokinetics in the Elderly:

Not applicable.

6. Nonclinical properties

6.1. Animal Toxicology or Pharmacology

Preclinical Safety Data:

- Mutagenicity

There is insufficient information to determine the mutagenic potential of the active ingredients.

- **Carcinogenicity**

There is insufficient information to determine the carcinogenic potential of the active ingredients.

- **Teratogenicity**

There is insufficient information to determine the teratogenic potential of the active ingredients.

7. Description

A clear dark pink to red coloured flavoured syrup with characteristic odour.

8. Pharmaceutical particulars

8.1. Incompatibilities

Not Applicable

8.2. Shelf-life

Refer pack

8.3. Packaging information

225ml/450ml Bottle

8.4. Storage and handling instructions

Store at a temperature not exceeding 25°C.

9. Patient Counselling Information

Take as prescribed by your physician.

Keep out of reach of children.

Always consult your doctor. Do not self-medicate.

What is a multivitamin?

Multivitamins are a combination of many different vitamins that are normally found in foods and other natural sources.

Multivitamins are used to provide vitamins that are not taken in through the diet. Multivitamins are also used to treat vitamin deficiencies (lack of vitamins) caused by illness and poor nutrition, digestive disorders, and other conditions.

Warnings

Seek emergency medical attention if you think you have used too much of multivitamins. An overdose of vitamins A, D, E, or K can cause serious or life-threatening side effects. Certain minerals contained in a multivitamin may also cause serious overdose symptoms if you take too much.

Before taking this medicine

Many vitamins can cause serious or life-threatening side effects if taken in large doses. Do not take more of this medicine than directed on the label or prescribed by your doctor.

Before you use multivitamins, tell your doctor about all your medical conditions and allergies.

How should I take multivitamins?

Use exactly as directed on the label, or as prescribed by your doctor.

Never take more than the recommended dose of a multivitamin. Avoid taking more than one multivitamin product at the same time unless your doctor tells you to. Taking similar vitamin products together can result in a vitamin overdose or serious side effects.

Many multivitamin products also contain minerals such as calcium, iron, magnesium, potassium, and zinc. Minerals (especially taken in large doses) can cause side effects such as tooth staining, increased urination, stomach bleeding, uneven heart rate, confusion, and muscle weakness or limp feeling. Read the label of any multivitamin product you take to make sure you are aware of what it contains.

Take your multivitamin with a full glass of water.

Measure liquid medicine carefully. Use the dosing syringe provided, or use a medicine dose-measuring device (not a kitchen spoon).

Store at a temperature not exceeding 30°C. Store multivitamins in their original container.

What happens if I miss a dose?

Consult your physician. Do not take two doses at one time.

What happens if I overdose?

Seek emergency medical attention

Overdose symptoms may include stomach pain, vomiting, diarrhea, constipation, loss of appetite, hair loss, peeling skin, tingling feeling in or around your mouth, weight loss, severe headache, muscle or joint pain, severe back pain, blood in your urine, pale skin, and easy bruising or bleeding.

What should I avoid while taking multivitamins?

Avoid taking more than one multivitamin product at the same time unless your doctor tells you to. Taking similar vitamin products together can result in a vitamin overdose or serious side effects.

Avoid the regular use of salt substitutes in your diet if your multivitamin contains potassium.

If you are on a low-salt diet, ask your doctor before taking a vitamin or mineral supplement.

Do not take multivitamins with milk, other dairy products, calcium supplements, or antacids that contain calcium. Calcium may make it harder for your body to absorb certain ingredients of the multivitamin.

Multivitamins side effects

Get emergency medical help if you have signs of an allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

When taken as directed, multivitamins are not expected to cause serious side effects. Common side effects may include:

upset stomach;

headache; or

unusual or unpleasant taste in your mouth.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects.

Multivitamin side effects (more detail)

What other drugs will affect multivitamins?

Multivitamins can interact with certain medications, or affect how medications work in your body. Ask a doctor or pharmacist if it is safe for you to use multivitamins if you are also using: tretinoin or isotretinoin; an antacid; an antibiotic; a diuretic or "water pill"; heart or blood pressure medications; a sulfa drug; or NSAIDs (nonsteroidal anti-inflammatory drugs) - ibuprofen (Advil, Motrin), naproxen (Aleve), celecoxib, diclofenac, indomethacin, meloxicam, and others.

10. Details of manufacturer

Manufactured by:

Tirupati Medicare Limited
Nahan Road, Paonta Sahib,
Dist. Sirmour 173 025 HP India.

Marketed by:

Abbott Healthcare Pvt. Ltd.
Angel Space, Bldg. D-4, Gala No. 1 to 3 &
11 to 13 Ground Floor, 101 to 106 & 111 to
116 First Floor, 201 to 206 & 211 to 216
2nd Floor, Pimpalas, Dist. Thane,
Bhiwandi - 421 302,
Maharashtra, India.

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11. Details of Permission or license number with date

Mfg. License No. MB/07/553, dated 30-Sep-24

12. Date of revision

Version 1.0 dated 22-Dec-25

For Product Complaints/Adverse events or Queries please write to
webmasterindia@abbott.com