

For the use of a for healthcare professional or a Hospital or a Laboratory only

I - VIT PRO CAPSULES

1. Generic Name

Grape Seed Extract, Multivitamin, Multimineral with Protein Hydrolysate Soft Gelatin Capsules

2. Qualitative and quantitative composition

Each soft gelatin capsule contains:		% RDA
Protein Hydrolysate.....	330 mg	**
Grape Seed Extract.....	50 mg	**
Niacin (Nicotinamide).....	14 mg	77.77
Zinc Oxide.....	10 mg	83.33
Pantothenic Acid (Calcium Pantothenate).....	5 mg	**
Manganese Sulphate.....	5 mg	100
Vitamin B ₆ (Pyridoxine Hydrochloride).....	2 mg	100
Copper (Cupric Sulphate).....	1.3 mg	96.29
Vitamin A (Retinol-all trans Retinol).....	1600 IU	80.00
Folic Acid (n-pteroyl-l-glutamic acid).....	100 mcg	100
Vitamin B ₁₂ (Cyanocobalamin).....	1 mcg	100
Excipients.....	q.s.	

%RDA calculated basis ICMR guidelines

** No RDA established

Other Ingredients: Hydrogenated Vegetable Oil, Bees Wax (901), Peanut Oil, BHA (320), BHT (321), Polysorbate 80 (432), Lecithin (322), Gelatin (428), Glycerin (422), Sorbitol (420i), Methyl paraben (218) and Propyl paraben (216).

CONTAINS PERMITTED SYNTHETIC FOOD COLOURS

(Ponceau 4R (124), Brilliant Blue (133), Sunset Yellow (110)).

Approved colours used in soft gelatin capsule shells.

Appropriate overages of vitamins are added to compensate for loss on storage.

3. Dosage form and strength

Dosage form: soft gelatin capsule

Strength: Protein Hydrosylate; 330 mg, Grape Seed Extract: 50 mg, Niacin (Nicotinamide) : 14 mg, Zinc Oxide, 10 mg, Pantothenic Acid (Calcium Pantothenate) : 5 mg, Manganese Sulphate : 5 mg, Vitamin B₆ (Pyridoxine Hydrochloride): 2 mg, Copper (Cupric Sulphate) : 1.3 mg, Vitamin A (Retinol-all trans Retinol) : 1600 IU, Folic Acid (n-pteroyl-l-glutamic acid): 100 mcg and Vitamin B₁₂ (Cyanocobalamin): 1 mcg

4. Clinical particulars

4.1 Therapeutic indication

Nutraceuticals

4.2 Posology and method of administration

- Recommended Dosage: One capsule daily after meal or as directed by healthcare professional

-Do not exceed the recommended serving size.

-Nutritional Information: (Serving per Gram)

Energy value	4.81	Kcal
Total fat	0.43	g
Carbohydrate	0.32	g
Protein	0.034	g
Sugar	0.003	g
Saturated Fatty Acid	0.027	g
Trans Fatty Acid	0000	g
Dietary Fibre	0.000	g

-Gelatin Food Grade

-Do not chew or crush the capsule, it should be swallowed whole with water.

-Not for medicinal use.

-Warning: Contains peanut oil, not recommended for people allergy to Peanut.

-Keep out of reach of children.

-This product is not intended to diagnose, treat, cure or prevent any disease.

- In case you are pregnant, lactating or taking any medication, consult your Healthcare Professional.

4.3 Contraindications

Haemochromatosis and other iron storage disorders.

Hypersensitivity to the active substance(s) or to any of the excipients.

Protein Substance (Inc Amino Acids)

Active liver disease or unexplained persistent elevations in hepatic transaminases

Patients with active peptic ulcer disease

Patients with arterial bleeding

None reported

4.4 Special warnings and precautions for use

No other vitamins, minerals or supplements with or without vitamin A should be taken with this preparation except under medical supervision.

No other vitamins, minerals or supplements with or without vitamin A should be taken with this preparation except under medical supervision.

Patients with thyroid disorders should seek medical advice before taking I-VIT PRO CAPSULES. An allowance should be made for vitamins or minerals obtained from other sources.

4.5 Drugs interactions

Folic acid can reduce the plasma concentration of phenytoin. Oral iron and zinc sulfate reduce the absorption of tetracyclines.

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

I-VIT PRO CAPSULES may be administered during pregnancy and lactation at the recommendation of the physician.

4.7 Effects on ability to drive and use machines

None anticipated.

4.8 Undesirable effects

Undesirable effects are listed by MedDRA System Organ Classes.

Assessment of undesirable effects is based on the following frequency groupings:

Very common: $\geq 1/10$

Common: $\geq 1/100$ to $< 1/10$

Uncommon: $\geq 1/1,000$ to $< 1/100$

Rare: $\geq 1/10,000$ to $< 1/1,000$

Very rare: $< 1/10,000$

Not known: cannot be estimated from the available data

Immune system disorders	<i>Not known:</i> Hypersensitivity reaction (such as rash)
Gastrointestinal disorders	<i>Not known:</i> Gastrointestinal disturbances (such as nausea, vomiting and abdominal pain)

4.9 Overdose

No cases of overdosage due to I-VIT PRO CAPSULES therapy have been reported. Any symptoms which may be observed due to the ingestion of large quantities of I-VIT PRO CAPSULES will be due to the fat soluble vitamin content.

5. Pharmacological properties

5.1 Mechanism of Action

5.2 Pharmacodynamic properties

The following account summarises the pharmacological effects of the vitamins and minerals in I-VIT PRO CAPSULES and describes the conditions caused by deficiency of these.

Vitamin A

Vitamin A plays an important role in the visual process. It is isomerised to the 11-cis isomer and subsequently bound to the opsin to form the photoreceptor for vision under subdued light. One of the earliest symptoms of deficiency is night blindness which may develop into the more serious condition xerophthalmia. Vitamin A also participates in the formation and maintenance of the integrity of epithelial tissues and mucous membranes. Deficiency may cause skin changes resulting in a dry rough skin with lowered resistance to minor skin infections. Deficiency of Vitamin A, usually accompanied by protein-energy malnutrition, is linked with a frequency of infection and with defective immunological defence mechanisms.

Vitamin B₆ (Pyridoxine)

Pyridoxine, once absorbed, is rapidly converted to the co-enzymes pyridoxal phosphate and pyridoxamine phosphate which play an essential role in protein metabolism. Convulsions and hypochromic anaemia have occurred in infants deficient in pyridoxine.

Vitamin B₁₂ (Cyanocobalamin)

Vitamin B₁₂ is present in the body mainly as Methylcobalamin and as adenosylcobalamin and hydroxocobalamin. These act as co-enzymes in the Trans methylation of homocysteine to methionine; in the isomerisation 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.

Nicotinamide

The biochemical functions of nicotinamide as NAD and NADP (nicotinamide adenine dinucleotide phosphate) include the degradation and synthesis of fatty acids, carbohydrates and amino acids as well as hydrogen transfer. Deficiency produces pellagra and mental neurological changes.

Pantothenic Acid

Pantothenic acid is incorporated into co-enzyme A and is involved in metabolic pathways involving acetylation which includes detoxification of drug molecules and biosynthesis of cholesterol, steroid hormones, Mucopolysaccharides and acetylcholine. CoA has an essential function in lipid metabolism.

Folic Acid

Folic acid is reduced in the body to tetrahydrofolate which is a co-enzyme for various metabolic processes, including the synthesis of purine and pyrimidine nucleotides and hence in the synthesis of DNA. It is also involved in some amino acid conversion and in the formation and utilisation of formate. Deficiency of folic acid leads to megaloblastic anaemia.

Copper (Copper Sulfate)

Traces of copper are essential to the body as constituents of enzyme systems involved in oxidation reactions.

Magnesium (Magnesium Oxide)

Magnesium is essential to the body as a constituent of skeletal structures and in maintaining cell integrity and fluid balance. It is utilised in many of the functions in which calcium is concerned but often exerts the opposite effect. Some enzymes require the magnesium ion as a co-factor.

Zinc (Zinc Sulfate)

Zinc is a constituent of many enzymes and is, therefore, essential to the body. It is present with insulin in the pancreas. It plays a role in DNA synthesis and cell division. Reported effects of deficiency include delayed puberty and hypo gonadal dwarfism.

Manganese (Manganese Sulfate)

Manganese is a constituent of enzyme systems including those involved in lipid synthesis, the tricarboxylic acid cycle and purine and pyrimidine metabolism. It is bound to arginase of the liver and activates many enzymes.

5.3 Pharmacokinetic properties

The following account describes the absorption and fate of each of the active constituents of I-VIT PRO CAPSULES .

Vitamin A

Except when liver function is impaired, Vitamin A is readily absorbed. β -carotene (as in I-VIT PRO CAPSULES) is Provitamin A and is the biological precursor to Vitamin A. It is converted to Vitamin A (Retinol) in the liver; retinol is emulsified by bile salts and phospholipids and absorbed in a micellar form. Part is conjugated with glucuronic acid in the kidney and part is metabolised in the liver and kidney, leaving 30 to 50% of the dose for storage in the liver. It is bound to a globulin in the blood. Metabolites of Vitamin A are excreted in the faeces and the urine.

Vitamin B₆ (Pyridoxine)

Pyridoxine is absorbed from the gastro-intestinal tract and converted to the active pyridoxal phosphate which is bound to plasma proteins. It is excreted in the urine as 4-pyridoxic acid.

Vitamin B₁₂ (Cyanocobalamin)

Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin B₁₂ showed it was quickly taken up by the intestinal mucosa and held there for 2 - 3 hours. Peak concentrations in the blood and tissues did not occur until 8 - 12 hours after dosage 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 a dose is excreted in the urine, most of it in the first eight hours.

Nicotinamide (Nicotinic Acid Amide)

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

Phosphorus (Calcium Hydrogen Phosphate)

The body contains from 600 - 800 g of phosphorus, over 80% of which is present in the bone as phosphate salts, mainly hydroxyapatite crystals. The phosphate in these crystals is available for exchange with phosphate ions in the extra-cellular fluids.

Folic Acid

Folic acid is absorbed mainly from the proximal part of the small intestine. Folate polyglutamates are considered to be deconjugated to monoglutamates during absorption. Folic acid rapidly appears in the blood where it is extensively bound to plasma proteins. Some folic acid is distributed in body tissues, some is excreted as folate in the urine and some is stored in the liver as folate.

Copper Sulfate (Copper)

Copper is absorbed from the gastro-intestinal tract and its major route of excretion is in the bile.

Magnesium Oxide (Magnesium)

Magnesium salts are poorly absorbed from the gastro-intestinal tract; however, sufficient magnesium will normally be absorbed to replace deficiency states. Magnesium is excreted in both the urine and the faeces but excretion is reduced in deficiency states.

Zinc Sulfate (Zinc)

Zinc is poorly absorbed from the gastro-intestinal tract. It is widely distributed throughout the body. It is excreted in the faeces with traces appearing in the urine.

Manganese Sulfate (Manganese)

Manganese salts are poorly absorbed.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

7. Description

Pink color oblong shape soft gelatin capsule filled with brown color medicament

8. Pharmaceutical particulars

8.1 Incompatibilities

Not applicable

8.2 Shelf-life

BEST BEFORE 18 MONTH FROM MANUFACTURE

8.3 Packaging information

Available in Blister strip of 15 Capsules

8.4 Storage and handing instructions

Store in a cool, dry place below 25°C Protect from Direct sunlight, Heat and Moisture.

9. Patient Counselling Information

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

The information in this leaflet has been divided into the following sections:

9.1. What I-VIT PRO CAPSULES are and what they are taken for

9.2. Check before you take I-VIT PRO CAPSULES

9.3. How to take I-VIT PRO CAPSULES

9.4. Possible side effects

9.5. How to store I-VIT PRO CAPSULES

9.6. Further information

9.1. What I-VIT PRO CAPSULES are and what they are taken for I-VIT PRO CAPSULES

I VIT PRO CAPSULES contains Nutritional Supplement (Protein Hydrolysate + Vitamins-Minerals+ Antioxidants) and is prescribed as a nutritional supplement.

9.2. Check before you take I-VIT PRO CAPSULES

- If you are allergic (hypersensitive) to any of the ingredients of I-VIT PRO CAPSULES
- If you suffer from iron storage disorders such as bronzed diabetes (haemochromatosis)

Do not give I-VIT PRO CAPSULES to children aged under 12.

Take special care with I-VIT PRO CAPSULES Before you are given I-VIT PRO CAPSULES tell your doctor, dietician or pharmacist if:

- You are pregnant or thinking of becoming pregnant
- You are a smoker
- You suffer from thyroid problems.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before taking I-VIT PRO CAPSULES

Taking other medicines

Tell your doctor if you are taking or have recently taken/used any of the following medicines as they may interfere with I-VIT PRO CAPSULES :

- Phenytoin (used to treat epilepsy)

Please tell your doctor if you are taking or have recently taken/used any other medicines including other vitamin or mineral products medicines obtained without a prescription.

Pregnancy and breast-feeding

I-VIT PRO CAPSULES contain vitamin A, check with your doctor, dietician or pharmacist for advice before taking this medicine during pregnancy. Check with your doctor or pharmacist for advice before taking this medicine whilst breast-feeding.

Warning: Contains peanut oil, not recommended for people allergy to Peanut.

-Keep out of reach of children.

-This product is not intended to diagnose, treat, cure or prevent any disease. In case you are pregnant, lactating or taking any medication, consult your Healthcare Professional.

Gelatin Food Grade

9.3. How to take I-VIT PRO CAPSULES

- Recommended Dosage: One capsule daily after meal or as directed by healthcare professional

-Do not exceed the recommended serving size.

-Do not chew or crush the capsule, it should be swallowed whole with water.

-Not for medicinal use.

What to do if you take more I-VIT PRO CAPSULES than you should

If you (or someone else) accidentally take too many tablets, you should tell your doctor at once or contact the nearest accident and emergency department. Show any leftover medicines or the empty packet to the doctor.

If you forget to take I-VIT PRO CAPSULES do not worry.

If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose (within 1-2 hours). Do not take a double dose. Then go on as before

9.4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. I-VIT PRO CAPSULES may cause allergic reactions (such as rash), and problems related to your stomach and intestines (such as feeling or being sick and stomach pains).

9.5. How to store I-VIT PRO CAPSULES

Store in a cool, dry place below 25°C. Protect from direct sunlight, heat & moisture.

-Keep out of reach of children

9.6. Further information

The active Ingredients are : Protein Hydrosylate; 330 mg, Grape Seed Extract: 50 mg, Niacin (Nicotinamide) : 14 mg, Zinc Oxide, 10 mg, Pantothenic Acid (Calcium Pantothenate) : 5 mg, Manganese Sulphate : 5 mg, Vitamin B₆ (Pyridoxine Hydrochloride), 2 mg, Copper (Cupric Sulphate) : 1.3 mg, Vitamin A (Retinol-all trans Retinol) : 1600 IU, Folic Acid (n-pteroyl-l-glutamic acid): 100 mcg and Vitamin B₁₂ (Cyanocobalamin) 1 mcg

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Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting. By reporting side effects, you can help provide more information on the safety of this medicine

10. Details of manufacturer

Elnova Pharma,

Vill: Rampur, Jattan, moginand, Nahan road, kala-amb, Dist: Sirmour (HP) 173030

11. Details of permission or licence number with date

Not Applicable

12. Date of revision

Not Applicable

MARKETED BY



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