

To be sold by retail on the prescription of Registered Medical Practitioner only.

BEVON SOFGEL

1. Generic Name

Multivitamin, Multimineral & Antioxidants Capsules

2. Qualitative and quantitative composition

Each soft gelatin capsule contains:

Pyridoxine hydrochloride IP.....	1.5 mg
Niacinamide IP.....	15 mg
Cyanocobalamin IP.....	0.5 mcg
Folic Acid IP.....	300 mcg
Biotin USP.....	30 mcg
Beta Carotene (30% dispersion) USP.....	5mg
Zinc Sulfate monohydrate IP equivalent to elemental Zinc.....	7.5mg
Sodium Selenate equivalent to selenium.....	30 mcg
Copper Sulfate pentahydrate BP equivalent to elemental copper	2.5mg
Chromium Chloride USP equivalent to elemental chromium.....	65 mcg
Manganese Chloride USP equivalent to elemental Manganese.....	1.4 mg
Choline Bitartrate USP.....	10 mg
Sodium Molybdate dehydrate BP equivalent to elemental Molybdenum.....	25 mcg
Sodium vanadate equivalent to elemental Vanadium.....	10 mcg
Benfothiamine.....	2 mg
Sodium Borate BP equivalent to elemental Boron.....	150 mcg
Nickel Sulfate equivalent to elemental nickel.....	5 mcg
Dibasic calcium Phosphate IP equivalent to elemental phosphorus.....	125 mg
Excipients	qs

In wheat germ oil virgin and flaxseed oil base.

3. Dosage form and strength

Soft gelatin capsule.

4. Clinical particulars

4.1 Therapeutic indication

For Vitamins and Mineral deficiency states in adult patients.

4.2 Posology and method of administration

Adults and the Elderly

One capsule daily.

Preferably taken one hour after meals. Do not exceed the stated dose. The capsule should be swallowed whole with water.

Children under 12 years of age

Bevon Capsules are not recommended for this age group.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in the formulation.

4.4 Special warnings and precautions for use

- Whilst taking Bevon Capsules both protein and energy are also required to provide complete nutrition in the daily diet. No other vitamins, minerals or supplements with or without vitamin A should be taken with this preparation except under medical supervision.

- Do not take Bevon Capsules on an empty stomach. Do not exceed the stated dose. Keep out of the reach of children. If symptoms persist, consult your doctor.
- Evidence from Randomised Control Trials suggests that high doses (20-30 mg/day) β -carotene intake may increase the risk of lung cancer in current smokers and those previously exposed to asbestos. This high-risk population should consider the potential risks and benefits of Bevon Capsules, which contain 5mg of β -carotene per recommended daily dose, before use.

4.5 Drugs interactions

Folic acid can reduce the plasma concentration of phenytoin. Zinc sulfate reduce the absorption of tetracyclines.

4.6 Use in special populations

Pregnancy and Breastfeeding

Bevon 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

Immune system disorders: Hypersensitivity reaction (such as rash)

Gastrointestinal disorders: Gastrointestinal disturbances (such as nausea, vomiting and abdominal pain).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via email to: *medico@zuventus.com*

Website: *<http://www.zuventus.co.in/safety.aspx>*

By reporting side effects, you can help provide more information on the safety of this medicine.

4.9 Overdose

No cases of overdosage due to Bevon therapy have been reported. In case of accidental overdose, discontinue use and seek professional assistance immediately. Any symptoms which may be observed due to the ingestion of large quantities of capsules will be due to the fat soluble vitamin content.

Gastric lavage may be necessary to remove drug already released into the stomach. Signs and symptoms such as gastrointestinal disorders like diarrhoea may be associated with an overdose of Bevon.

5 Pharmacological properties

5.1 Pharmacodynamic properties / Mechanism of Action

Beta Carotene

β -carotene is the most prominent and efficient member of the group of carotenoids (natural colorants that occur in the human diet). Carotenoids are red, orange, or yellow, fat-soluble compounds. Alpha, beta, and gamma carotene are considered provitamins because they can be converted to active vitamin A. Beta-carotene is converted to retinol, which is essential for vision and growth.

ROS-induced oxidative stress is suggested as being basic to several human diseases. β -carotene has a unique type of antioxidant activity. Beta carotene traps free radicals and studies suggest that it may also reduce tumor development. Studies have shown that vitamin A is essential to the normal growth of epithelial tissues.

Pyridoxine hydrochloride

The active coenzyme form of vitamin B6 (Pyridoxine) is pyridoxal 5'-phosphate. Approximately 80% of the body's total vitamin B6 is present as pyridoxal phosphate in muscle. Pyridoxal phosphate is a coenzyme for many enzymes involved in amino acid metabolism. It is also the co-factor for glycogen phosphorylase, where the phosphate group is catalytically important.

Vitamin B6 helps the body to make several neurotransmitters. It is needed for normal brain development and function, and helps the body to make the hormones serotonin and norepinephrine, which influence mood, and melatonin, which helps to regulate the body clock. Along with vitamins B12 and B9 (folic acid), B6 helps to control levels of homocysteine in the blood. In addition, vitamin B6 is important in steroid hormone action where it removes the hormone-receptor complex from DNA binding, terminating the action of the hormones. In vitamin B6 deficiency, this results in increased sensitivity to the actions of low concentrations of estrogens, androgens, cortisol and vitamin D.

Folic Acid

Folate is a water-soluble B-vitamin and enzymatic cofactor that is necessary for the synthesis of purine and thymidine nucleotides as well as for synthesis of

methionine from homocysteine. Tetrahydrofolate (TH₄-folate) is the biologically active form of folic acid. The main role of folic acid in biochemistry is the single-carbon transfer reaction (e.g. transfer of a methyl, methylene, or formyl group). Folic acid is involved in the transformation of certain amino acids as well as in the synthesis of purines and dTMP (2'-deoxythymidine-5'-phosphate) needed for the synthesis of nucleic acid (DNA), required by all rapidly growing cells. In humans, folate deficiency results in serious pathologies, the most important of which are neural tube defects, megaloblastic anemia, acceleration of the arteriosclerotic process, changes in the central nervous system, and the development of certain types of cancer.

Cyanocobalamin

Vitamin B₁₂ is found only in foods of animal origin. Vitamin B₁₂ is essential for cellular DNA synthesis and hence contributes to functions of various tissues of the body, formation of myelin sheath, more so the rapidly dividing and proliferating cellular systems such as blood and gastric epithelium. The absorbed inert form of cyanocobalamin is converted into two important active forms. One is methylcobalamin—involved in maturation of red blood corpuscles. The second active form is adenosylcobalamin involved in healthy myelination and neuronal integrity. Methylcobalamin deficiency leads to folate trap resulting in megaloblastic anemia. Deficiency of adenosylcobalamin leads to accumulation of large amount of methylmalonyl-CoA resulting in synthesis and incorporation of nonphysiological fatty acids into neuronal lipids, causing, demyelination, axonal degeneration and neuronal death leading to neurological complications.

Zinc Sulfate

Zinc is an essential trace mineral necessary for the proper function of about 300 different enzymes. Therefore, zinc plays a role in virtually all biochemical pathways and physiological processes in the body. Thirty percent of the body's zinc is stored in the bones and 60% in muscles. The other 10% is found in virtually all body tissues. Zinc is important for wound healing, immune system support and to increase fertility (sperm production). It also assists digestion, energy production, growth, cellular repair, collagen synthesis, bone strength, cognitive function, and carbohydrate metabolism (glucose utilization and insulin production). Zinc not only modulates cell-mediated immunity but is also an antioxidant and anti-inflammatory agent. Mild zinc deficiencies are currently thought to cause chronic metabolic derangement leading to or exacerbating immune deficiency, gastrointestinal problems, endocrine disorders, neurologic dysfunction, cancer, accelerated aging, degenerative disease, and more.

Niacinamide

Niacin was discovered as a nutrient during studies of pellagra. It is not strictly a vitamin since it can be synthesized in the body from the essential amino acid tryptophan. Two compounds, nicotinic acid and nicotinamide, have the biologic activity of niacin; its metabolic function is as the nicotinamide ring of the coenzymes NAD and NADP in oxidation-reduction reactions. Nicotinamide has important role in DNA repair mechanism.

Biotin

Biotin (Vitamin B7 or H) is a water soluble B vitamin that is essential for bodily health. It helps the body to process fat and sugars, and it helps form a critical process in fat production in the body. Biotin is involved in a number of carboxylase reactions. Biotin is often recommended as a dietary supplement

for healthy skin, hair and nails. Biotin deficiency is characterized by development of a fine scaly dermatitis, hair loss, conjunctivitis, ataxia and delayed development.

Sodium Molybdate dehydrate

Molybdenum belongs to a group of essential microelements. Molybdenum-containing enzymes catalyze basic metabolic reactions in the nitrogen, sulfur, and carbon cycles and are important for variety of metabolic pathways.

Copper Sulfate pentahydrate

Copper is a trace element present in all tissues and is required for cellular respiration, peptide amidation, neurotransmitter biosynthesis, pigment formation, and connective tissue strength. Copper is a cofactor for numerous enzymes and plays an important role in central nervous system development. Copper is essential for brain development during foetal and post-natal growth, and maintenance of brain health throughout life (including effective anti-oxidative defence), efficient communication between nerve cells, maintenance of healthy skin and connective tissue, wound healing, structural integrity and function of heart and blood vessels, growth of new blood vessels, proper structure and function of circulating blood cells, formation of the cells of immune system, maintenance of a healthy and effective immune response and generation and storage of energy in the mitochondria

Sodium Selenate

Selenium is incorporated into selenoproteins that have a wide range of pleiotropic effects, ranging from antioxidant, immune functions and anti-inflammatory effects to the production of active thyroid hormone. Low

selenium status has been associated with increased risk of mortality, poor immune function, and cognitive decline. Selenium supplementation has antiviral effects, is essential for male and female reproduction, and reduces the risk of autoimmune thyroid disease. Prospective studies have generally shown some benefit of higher selenium status on the risk of various cancers.

Chromium Chloride

Chromium is a critical cofactor in the action of insulin. Results from some trials have indicated that chromium supplementation increases muscle gain and fat loss associated with exercise and improves glucose metabolism and the serum lipid profile in patients with or without diabetes. Low chromium levels can increase blood sugar, triglycerides, cholesterol levels, and increase the risk for a number of conditions, such as diabetes and heart disease.

Manganese Chloride

Manganese is an essential element for humans and is required for growth, development, and maintenance of health. Manganese is necessary for a variety of metabolic functions including those involved in skeletal system development, energy metabolism, activation of certain enzymes, nervous system function, immunological system function, and reproductive hormone function. It is an antioxidant that protects cells from damage due to free radicals. Manganese also plays an essential role in regulation of cellular energy, bone and connective tissue growth and blood clotting. In the brain, Manganese is an important cofactor for a variety of enzymes, including the antioxidant enzyme superoxide dismutase, as well as enzymes involved in neurotransmitter synthesis and metabolism.

Choline Bitartrate

Choline is a component of phosphatidylcholine, acetylcholine, lecithin, sphingomyelin, cell membranes, plasma lipoproteins and platelet activating factors. Lecithin and sphingomyelin participate in signal transduction, an essential process for cell growth, regulation and function.

Sodium vanadate

Vanadium is a biologically important metal that is essential for normal cell function and development. Vanadium helps to maintain blood-sugar levels in the normal range by its insulin-like effects in the liver, skeletal muscle and adipose tissue. It affects cholesterol and triglyceride metabolism, influences the shape of erythrocytes, and stimulates glucose oxidation and glycogen synthesis in the liver. Its primary mode of action is as a cofactor that enhances or inhibits enzymes.

Benfotiamine

Thiamine (Vitamin B1) is considered as an essential micronutrient for humans. Due to the low bioavailability of the hydrosoluble forms of thiamine, its liposoluble preparations (benfotiamine) are preferentially used. Benfotiamine, a lipid-soluble analogue of vitamin B1, is a potent antioxidant that is used as a food supplement. Once thiamine enters the cells, it is phosphorylated by thiamine pyrophosphokinase (TPPK), and converted into the coenzyme thiamine pyrophosphate (TPP), the active form of thiamine. TPP is a relevant cofactor for various enzymes fundamental for glucose metabolism. Recent evidences have shown that the administration of thiamine or lipid-soluble derivatives, such as benfotiamine, has positive effects in the diabetic patients. Numerous studies have shown that benfotiamine inhibits three major pathways that lead to the formation of toxic substances such as advanced glycation end products (AGEs).

Sodium Borate

Boron is a trace element which has an important influence on both calcium and magnesium metabolism. Boron is concentrated in the bone, spleen and thyroid indicating boron's functions in bone metabolism and suggesting its potential role in hormone metabolism. Boron is thought to be useful to increase muscle mass; increase muscle strength; maintain bone density; improve calcium absorption and decrease body fat. According to the USFDA, boron is a trace mineral that helps bones to develop and grow normally.

Boron supplementation prevent atherosclerosis, improve brain function and cognitive functioning, reduce HDL cholesterol, affect thyroid hormone levels, alleviate harmful effects of vitamin D, magnesium, and potassium deficiency in postmenopausal bone loss, play a role in the prevention of osteoporosis and prevent calcium loss in postmenopausal women.

Nickel Sulfate

Nickel is a trace mineral that is required by body, but only in very small amount. Small amounts of nickel are found in DNA and RNA. Nickel plays a role in the circulation of some proteins and contributes to the production of hormones, lipids, and cell membranes. Nickel is also used to break down glucose for energy.

Dibasic calcium Phosphate

Next to calcium, phosphorus is the most abundant mineral in the body. These 2 important nutrients work closely together to build strong bones and teeth. Phosphorus, an essential mineral, is naturally present in many foods and available as a dietary supplement. Phosphorus is a component of bones, teeth, DNA, and RNA. About 85% of phosphorus can be found in bones and teeth, but

it is also present in cells and tissues throughout the body. The health benefits of phosphorous include healthy bone formation, provide strength to bones and teeth, improved digestion, regulated excretion, protein formation, hormonal balance, improved energy extraction, cellular repair, optimized chemical reactions and proper nutrient utilization.

Phosphorus deficiency (hypophosphatemia) is rare in the United States and is almost never the result of low dietary intakes. The effects of hypophosphatemia can include anorexia, anemia, proximal muscle weakness, skeletal effects (bone pain, rickets, and osteomalacia), increased infection risk, paresthesias, ataxia, and confusion. In most cases, hypophosphatemia is caused by medical conditions, such as hyperparathyroidism, kidney tubule defects, and diabetic ketoacidosis.

5.2 Pharmacokinetic properties

Beta carotene

Except when liver function is impaired, Vitamin A is readily absorbed. β -carotene (as in Bevon 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.

Pyridoxine hydrochloride

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.

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.

Dibasic calcium 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.

Zinc Sulfate

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.

Biotin

Following absorption, biotin is stored in the liver, kidney and pancreas.

Sodium Selenate

Although it has been established that selenium is essential to human life, very little information is available on its function and metabolism.

Chromium Chloride

Most chromium compounds are soluble at the pH of the stomach, but less soluble hydroxides may form as pH is increased. The environment of the gastrointestinal tract and ligands provided by foods and supplements are important for mineral absorption.

Sodium Molybdate dehydrate

In humans, molybdenum is known to function as a cofactor for four enzymes: Sulfite oxidase catalyzes the transformation of sulfite to sulfate, a reaction that is necessary for the metabolism of sulfur-containing amino acids (methionine and cysteine).

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Nickel Sulfate

Nickel plays a role in the circulation of some proteins and contributes to the production of hormones, lipids, and cell membranes. Nickel is also used to break down glucose for energy.

Nickel serve as a cofactor or structural component of specific metalloenzymes of various functions, including hydrolysis and redox reactions and gene expression. Also serve as a cofactor facilitating ferric iron absorption or metabolism. Nickel is necessary for the biosynthesis of the hydrogenase, carbon monoxide dehydrogenase, and of factor F-430.

Nickel is a constituent part of all organs of vertebrates. Small amounts of nickel are found in DNA and RNA. Nickel therefore performs a vital function in metabolism and it is an essential element.

Sodium vanadate

Vanadium helps to maintain blood-sugar levels in the normal range by its insulin-like effects (mimics insulin) in the liver, skeletal muscle and adipose tissue.

Vanadium complexes are cofactors for several enzymes and also exhibit insulin-mimetic properties involved in

- regulation of glucose metabolism, including in diabetic patients
- regulation blood pressure (normalize BP)
- play a key role in the metabolism of the thyroid and of iron
- regulation of total cholesterol, HDL and triglyceride (TG) levels in blood

Sodium Borate

Studies with humans indicate that about 90 percent of boron is absorbed in the normal intake range. Most dietary boron is hydrolysed within the gut to yield $B(OH)_3$ which, as a neutral compound, is easily absorbed. Boron chemistry

suggests it is transported in the blood as $B(OH)_3$. Specifically, because boron forms labile complexes in aqueous solution, transport is probably as free boric acid rather than a complex. The blood boron concentration is dependent on dietary intake as primarily shown by animal studies.

Benfotiamine

Thiamine is absorbed from the gastro-intestinal tract and is widely distributed to most body tissues. Amounts in excess of the body's requirements are not stored but excreted in the urine as unchanged thiamine or its metabolites.

Niacinamide

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

Copper

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

Manganese Chloride

Manganese salts are poorly absorbed.

Choline Bitartrate

Very little information is available on its function and metabolism.

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 prescribing information.

7 Description

Bevon capsules contain a comprehensive formula of vitamins, minerals and antioxidants specially designed to support health and well-being in adults by unlocking energy and strengthening immunity. Most vitamins, minerals and trace elements are not produced by human body and hence are dependent on dietary supply of these nutrients. Since vitamins, minerals and trace elements are involved in many metabolic processes in the body, an adequate supply of these vital substances contribute to physical and mental well being.

8 Pharmaceutical particulars

8.1 Incompatibilities

No major incompatibilities are known.

8.2 Shelf-life

24 months

8.3 Packaging information

A blister strip of 15 capsules.

8.4 Storage and handing instructions

Store in a cool & dry place. Protect from light.

Keep out of reach of children.

9 Patient Counselling Information

Do not take Bevon Capsules:

- if you are allergic (hypersensitive) to any of the ingredients of Bevon Capsules
- if you suffer from hypercalcaemia (high level of calcium in the blood)

- Do not give Bevon Capsules to children aged under 12.

Take special care with Bevon Capsules

Before you are given Bevon Capsules tell your doctor, dietician or pharmacist if:

- you are pregnant or thinking of becoming pregnant
- you are a smoker

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before taking Bevon 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 Bevon Capsules:

- Phenytoin (used to treat epilepsy)
- Tetracycline antibiotics (used to treat infections) such as doxycycline and minocycline.

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.

10 Details of manufacturer

Olive Healthcare

197/2, Athiyawad, Dabhel Village, Nani Daman (U.T.) - 396 210.

11 Details of permission or licence number with date

DD/289 dated 16 July 2018

12 Date of revision

06/10/2021

