

## Vitasmith-D

### Vitamin C, Zinc & Vitamin D3 Soft Gelatin Capsules

#### COMPOSITION:

Each soft gelatin capsule contains:

Ascorbic Acid BP 500 mg  
(Vitamin C)

Zinc Sulfate Monohydrate BP  
equivalent to elemental Zinc 15 mg

Vitamin D3 BP 1000 IU

Excipients q.s.

Approved colours used in soft gelatin capsule shell

#### PHARMACODYNAMIC:

##### Pharmacotherapeutic Group Vitamin Supplement Pharmacodynamics Properties:

##### Vitamin C

Ascorbic acid is an important water-soluble vitamin and antioxidant. Due to the low storage capacity of the body for vitamin C, a regular intake of sufficient amounts is essential to humans.

Ascorbic acid and its metabolite dehydroascorbic acid form a reversible redox system that is involved in many enzymatic reactions and forms the basis for the spectrum of action of vitamin C. Ascorbic acid functions as a cofactor in a number of hydroxylation and amidation reactions by transferring electrons to enzymes that provide reducing equivalents.

The importance of ascorbic acid to the human body is most clearly evident in lincally manifest vitamin C deficiency, i.e. scurvy. Ascorbic acid plays a key role in the production of hydroxyproline from proline, which in turn is essential to the development of functionally active collagen.

The symptoms seen in scurvy, such as delayed wound healing, disturbances of bone growth, vascular fragility, and disorders of dentine formation, are the result of impaired collagen formation.

##### Zinc:

As with vitamin C, low levels of zinc may also adversely affect the healing rate of wounds, ulcers and decubitus. Zinc status is of major importance in maintenance of effective immune response, particularly T-cell-mediated response.

##### Vitamin D3:

In its biologically active form vitamin D stimulates intestinal calcium absorption, incorporation of calcium into the osteoid, and release of calcium 3 from bone tissue. In the small intestine it promotes rapid and delayed calcium uptake. The passive and active transport of phosphate is also stimulated. In the kidney, it inhibits the excretion of calcium and phosphate by promoting tubular resorption. The production of parathyroid hormone (PTH) in the parathyroids is inhibited directly by the biologically active form of vitamin D. PTH secretion is inhibited additionally by 3 the increased calcium uptake in the small intestine under the influence of biologically active vitamin D3.

##### Pharmacokinetics:

*Absorption:* Ascorbic acid is absorbed primarily in the upper part of the small intestine via sodium-dependent

active transport. When ascorbic acid is present in high concentrations, uptake occurs by means of passive diffusion. After oral administration of doses of 1-12 g, the proportion of ascorbic acid absorbed falls from approximately 50% to about 15%, though the absolute quantity of substance taken up continues to increase.

Zinc is absorbed all along the small intestine. The absorption of zinc (ionic) administered in solution on an empty stomach ranges from 41-79%, while the zinc present in foods or that given as a supplement with meals is absorbed in the range of 10-40%.

*Distribution:* The physiological body pool of vitamin C is about 1500 mg. Plasma protein binding of ascorbic acid is approximately 24%. Serum concentrations are normally 10 mg/l (60 µmol/l). Concentrations below 6 mg/l (35 µmol/l) indicate that the intake of vitamin C is not always adequate, and concentrations below 4 mg/l (20 µmol/l) indicate that the intake is actually inadequate. In clinically manifest scurvy, serum concentrations are below 2 mg/l (10 µmol/l).

Total body zinc content is controlled in part by regulating the efficiency of intestinal absorption and the excretion from endogenous zinc pools to maintain zinc homeostasis. The adult total body zinc content ranges from about 2.3 mmol (1.5 g) in women to 3.8 mmol (2.5 g) in men. Zinc is present in all organs, tissues, fluids, and secretions of the body. Zinc is primarily an intracellular ion, with well over 95% of the total-body zinc found within cells. Zinc is associated with all organelles of the cell, but about 60 to 80% of the cellular zinc is found in the cytosol.

*Metabolism:* Ascorbic acid is metabolised partly via dehydroascorbic acid to oxalic acid and other products. When ingested in excessive quantities, however, ascorbic acid is largely excreted in unchanged form in the urine and faeces. Ascorbic-acid-2-sulphate also appears as a metabolite in the urine. The total amount of zinc present in the major tissues is much larger than the total in plasma. Thus, relatively small variations in zinc content of tissues, such as the liver, can have dramatic effects on the plasma zinc. All absorbed zinc passes through the plasma to the tissues, and the flux of zinc through the plasma is said to be replaced approximately 130 times per day. There is no specific zinc "store". Human experimental studies with low-zinc diets 2.6-3.6 mg/day /40-55 mmol/day) have shown that circulating zinc levels and activities of zinc-containing enzymes can be maintained within normal range over several months highlighting the efficiency of the zinc homeostasis mechanism.

*Elimination:* The physiological body pool of ascorbic acid is about 1500 mg. The elimination half-life of ascorbic acid depends on the route of administration, the quantity administered and the rate of absorption. Following an oral dose of 1 g the half-life is about 13 hours. When 1-3 g vitamin C /day is taken, the main route of excretion is renal. With doses exceeding 3 g, increasing quantities are excreted unchanged in the faeces.

The major route for endogenous zinc excretion is into the gastrointestinal tract with ultimate loss in the faeces. When tracer doses of zinc are given either orally or intravenously, only about 2 to 10% is recovered in the urine; the remainder is lost in the faeces. In humans,

endogenous faecal losses may range from <15 µmol/day (1 mg/day) with extremely low intakes to over 80 µmol/day (5 mg/day) with extremely high intakes. Normally, about 6 to 9 µmol (400 to 600 µg) of zinc is excreted daily in the urine.

Vitamin D is well absorbed from the gastro-intestinal tract in the presence of bile. It is hydroxylated in the liver to form 25-hydroxycolecalciferol and then undergoes further hydroxylation in the kidney to form the active metabolite 1, 25 dihydroxycolecalciferol (calcitriol). The metabolites circulate in the blood bound to a specific  $\alpha$ -globin, Vitamin D and its metabolites are excreted mainly in the bile and faeces.

#### INDICATION:

Vitasmith-D (Vitamin C, Zinc & Vitamin D Soft Gelatin Capsules) supports the immune system to fight against various diseases and prevents nutritional deficiencies. It is composed of Vitamin C (Ascorbic acid), Vitamin D (Cholecalciferol), and Zinc. Vitamin C is an antioxidant that prevents cell damage and boosts immunity. It prevents scurvy, a condition caused due to low Vitamin C levels in the body that causes anaemia, rashes, weakness, and fatigue. Vitamin D is used to treat and prevent bone disorders, such as rickets and osteomalacia. It also reduces inflammation and promotes neuromuscular and immune functions. Zinc is a mineral that promotes the growth and development of body tissues. It is essential for vision, fighting against rhinoviruses (that cause the common cold), immune function, bone metabolism, taste, wound healing, insulin production, blood clotting, and thyroid function.

#### DOSAGE AND METHOD OF ADMINISTRATION:

##### Dosage

Take the capsule of Vitasmith-D with or without food or as directed by the Physician.

##### Method of Administration:

Oral use.

The capsule must be swallowed whole and take it with or without food at regular intervals, as prescribed by the doctor. Do not crush, chew or break it.

#### SPECIAL WARNING AND PRECAUTION FOR USE:

Let your doctor know if you are allergic to Vitasmith-D or its inactive components. Brief your medical history to the doctor if you have any heart/kidney/liver diseases before starting Vitasmith-D. Pregnant or breastfeeding women should consult their doctor before taking Vitasmith-D. It is advised to limit the alcohol intake while using Vitasmith-D. Vitasmith-D is safe to use in children when prescribed by the doctor. Do not store Vitasmith-D above 25°C.

#### CONTRAINDICATION:

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

#### DRUG INTERACTIONS:

*Drug-Drug Interaction:* Vitasmith-D may interact with

antibiotics (minocycline, tetracycline, demeclocycline, ciprofloxacin, norfloxacin), antirheumatics (penicillamine), anti-cancer drugs (cisplatin), and water pills (amiloride).

*Drug-Food Interaction:* It is advised to limit alcohol intake while using Vitasmith-D.

*Drug-Disease Interaction:* Vitasmith-D should be used with caution in heart, liver or kidney diseases. Please seek medical advice if you have any pre-existing medical conditions.

#### PREGNACY AND LACTATION:

During pregnancy, use this medicine only when advised by your doctor. Also, inform your doctor if you are planning to conceive before starting Vitasmith-D.

**LACTATION** It is not known if Vitasmith-D affects breastfeeding. Please consult your doctor before taking this medicine if you are a nursing mother.

#### UNDESIRABLE EFFECTS:

Undesirable Effects of Vitasmith-D:

- Diarrhoea
- Nausea
- Vomiting

#### EFFECT ON ABILITY TO DRIVE OR TO USE MACHINES:

The product has no or negligible influence on the ability to drive and use machines.

#### OVERDOSE:

There is no evidence that this product can lead to an overdose when used as recommended.

#### INCOMPATIBILITY:

None

#### STORAGE CONDITION:

Store at a temperature below 25°C. Protect from direct sunlight, heat and moisture.

**Keep the medicine out of reach of children.**

#### SHELF LIFE:

2 Years

#### PRESENTATION:

10 Soft gelatin capsules packed in Alu-PVC blister and such 3 blisters are packed in printed carton along with pack insert.

#### MANUFACTURED IN INDIA BY : DR. SMITHS BIOTECH PVT. LTD.

(An ISO 9001:2015 & WHO GMP Certified Co.)  
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