

Summary of Product Characteristics

IMMUNEZE

1. Name of the Medicinal Product

1.1 Product Name

IMMUNEZE

1.2 Strength

Vitamin C (as Ascorbic acid)	500 mg
Vitamin D3 (as Cholecalciferol)	400 IU
Zinc (as Zinc oxide)	15 mg

1.3 Pharmaceutical Dosage Form

Film-coated tablets

2. Qualitative and Quantitative Composition

2.1 Qualitative Declaration

2.2 Quantitative Declaration

Each tablet contains

Vitamin C (as Ascorbic acid)	500 mg
Vitamin D3 (as Cholecalciferol)	400 IU
Zinc (as Zinc oxide)	15 mg

For a full list of excipients, see section 6.1.

3. Pharmaceutical Form

Oval shaped, white film-coated tablets

4. Clinical Particulars

4.1 Therapeutic indications

- Treatment or prevention of vitamin C, vitamin D, and zinc deficiencies.

4.2 Posology and method of administration

Posology

For adult, the elderly and children over 4 years

Take 1 – 2 tablets daily with meal or as directed by a physician.

For children under 4 years

Consults a physician before using IMMUNEZE

Method of administration

Oral administration. Swallow the tablet whole with a full glass of water or other liquid. Do not chew the tablets.

4.3 Contraindications

Hypersensitivity or intolerance to any component of the product and should not be given to patients with hyperoxaluria, iron storage disorder disease (thalassaemia, haemochromatosis, sideroblastic anaemia) or other medical conditions that predispose individuals to iron overload, hypervitaminosis D, nephrolithiasis, hypercalcaemia and/or hypercalciuria, severe renal impairment, and copper deficiency.

4.4 Special warnings and precautions for use

Vitamin C may interfere with tests and assays for urinary glucose with methods utilizing glucose oxidase with indicator and neocuproin methods. Estimation of uric acid by phosphotungstate or uricase with copper reduction and measurement of creatinine in non-deproteinised serum may also be affected. High doses of vitamin C may give false-negative readings in faecal occult blood tests.

Vitamin D3 and Zinc should be used with caution in patients with impairment of renal function.

For Vitamin D3, the effect on calcium and phosphate levels should be monitored. The risk of soft tissue calcification should be taken into account. In patients with severe renal insufficiency other forms of vitamin D should be used and caution is required in patients suffering from sarcoidosis.

The product may accumulate in the body and cause toxicity. Therefore, it should not be used in excess of the prescribed dosage or used for a long period of time. Use this product as directed by healthcare professional only.

4.5 Interaction with other medicinal products and other forms of interaction

Interaction may cause of ascorbic acid, vitamin D3, or Zinc.

Vitamin C

Large doses of vitamin C may cause acidification of the urine which could alter the rate of renal excretion of some drugs. Vitamin C may increase the oral absorption of iron. It may also increase iron excretion when used in conjunction with desferrioxamine in the treatment of iron overload.

Vitamin D3

Concomitant treatment with phenytoin, barbiturates, glucocorticoids can decrease the effect of vitamin D.

Simultaneous treatment with ion exchange resins such as cholestyramine or laxatives such as paraffin oil may reduce the gastrointestinal absorption of vitamin D.

The cytotoxic agent actinomycin and imidazole antifungal agents interfere with vitamin D activity by inhibiting the conversion of 25-hydroxyvitamin D to 1,25-dihydroxyvitamin D.

Zinc

Zinc may inhibit the absorption of copper, reduce the absorption of quinolones; ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin.

The absorption of zinc may be reduced by tetracyclines, calcium salts, oral iron, penicillamine, and trientine (also the absorption of tetracyclines, oral iron, penicillamine, and trientine may be reduced by zinc). For tetracyclines, when both are being given an interval of at least three hours should be allowed.

4.6 Pregnancy and lactation

Pregnant and lactation women should exercise caution and follow the advice of the physician since there are no or limited amount of data in pregnant women. Zinc and vitamin C can cross the placenta. Vitamin C, vitamin D, and zinc are excreted in breast milk.

4.7 Effects on ability to drive and use machines

IMMUNEZE has no influence on ability to drive and use machines.

4.8 Undesirable effects

Undesirable effect may occur from vitamin C, vitamin D3, or Zinc.

Vitamin C

Vitamin C has been implicated in precipitating haemolytic anaemia in certain individuals with a deficiency of glucose-6-phosphate dehydrogenase. Increased intake of vitamin C over a prolonged period may result in an increase in renal clearance of vitamin C, and deficiency may result if the intake is reduced or withdrawn rapidly. Doses of more than 600 mg daily have a diuretic effect.

Vitamin D3

Uncommon undesirable effects (>1/1,000, <1/100) from vitamin D3 are hypercalcaemia and hypercalciuria and rare undesirable effects (>1/10,000, <1/1,000) are pruritus, rash, and urticarial.

Zinc

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.

Zinc may interfere with the absorption of copper, leading to reduced copper levels, and potentially copper deficiency. The risk of copper deficiency may be greater with long-term treatment and/or with higher doses of zinc.

4.9 Overdose

No case of over dosage in recommended dose has been report.

In case large doses of Vitamin C may cause diarrhoea and the formation of renal oxylate calculi. Symptomatic treatment may be required.

In case large doses of Vitamin D, the most serious consequence is hypercalcaemia. Symptoms may include nausea, vomiting, polyuria, anorexia, weakness, apathy, thirst and constipation. Treatment should consist of stopping all intake vitamin D and of rehydration.

In case large doses of Zinc may cause nausea; severe vomiting; dehydration; restlessness; sider blastic anemia (secondary to zinc-induced copper deficiency). Treatment should be reduce dosage or discontinue.

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Ascorbic acid coupled with dehydroascorbic acid to which it is reversibly oxidised, has a variety of functions in cellular oxidation processes and required in several important hydroxylations. Vitamin C appears to have an important role in metal ion metabolism. There is also evidence that vitamin C is required for normal leukocyte function and that it participates in the detoxification of numerous foreign substances by the hepatic microsomal system.

In its biologically active form vitamin D₃ stimulates intestinal calcium absorption, incorporation of calcium into the osteoid, and release of calcium from bone tissue. 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 D₃ and by the increased calcium uptake in the small intestine.

Zinc is an essential trace element involved in many enzyme systems. It may also have immunomodulatory activity, antioxidant activity, putative antiviral, fertility enhancing and retinoprotective activities.

5.2 Pharmacokinetic properties

Vitamin C is well absorbed from the gastro-intestinal tract, and is widely distributed to all tissues. Body stores of vitamin C normally are about 1.5 grams. The concentration is higher in leukocytes and platelets than in erythrocytes and plasma. Vitamin C additional to the body's needs (generally amounts above 200mg daily) is rapidly eliminated; unmetabolised vitamin C and its inactive metabolic products are chiefly excreted 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 α -globin, Vitamin D and its metabolites are excreted mainly in the bile and faeces.

Zinc is absorbed from the gastrointestinal tract and distributed throughout the body. 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 110 μ g/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.

5.3 Preclinical safety data

Vitamin C, vitamin D, and zinc are well known and widely-used material, which has been used in clinical practice for many years. There are no pre-clinical data of relevance are additional to that are already included in other sections.

6. Pharmaceutical Particulars

6.1 List of excipients

Microcrystalline cellulose, Crospovidone, Silicon Dioxide, Magnesium stearate, Opadry II White 85G58923

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Two years from manufacturing date

6.4 Special precautions for storage

Store below 30°C in a dry place, away from direct sunlight.

6.5 Nature and contents of container

Tablet in plastic bottle packed containing 30 and 60 tablets and unit carton containing 3x10 and 5x10 tablets blister packed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing Authorization Holder

MEGA LIFESCIENCES Public Company Limited
Samutprakarn, Thailand

8. Marketing Authorization Number

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9. Date of First Authorization/Renewal of the Authorization

DD/MM/YYYY

10. Date of Revision of the Text

DD/MM/YYYY