



National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1 NAME OF THE MEDICINAL PRODUCT

REMGVITE TABLET 100mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Ascorbic Acid	100 mg
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Excipients	q.s.
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3 PHARMACEUTICAL FORMS

Oral tablets

4 CLINICAL PARTICULARS

4.1 Therapeutic Indication.

Treatment of vitamin C and zinc deficiency.

4.2 Posology and method of administration.

Posology

Treatment of scurvy:

The optimal dose has not been established. For information:

- Child 1 month to 11 years: 100 mg 3 times daily
- Child 12 years and over and adult: 250 mg 3 times daily

or

- Child 1 month to 3 years: 100 mg 2 times daily
- Child 4 to 11 years: 250 mg 2 times daily
- Child 12 years and over and adult : 500 mg 2 times daily

Treatment is administered at least 2 weeks or longer (until symptoms resolve), then preventive treatment is given as long as the situation requires.

Prevention of scurvy:

Child and adult: 50 mg daily, as long as the situation requires

Method of administration

Tablet for oral administration.

4.3 Contraindications

Ascorbic Acid is contraindicated in patients with:

- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.

Patients suffering from or having a history of Nephrolithiasis must not take this product.

Patients suffering from oxalate urolithiasis or oxaluria must not take this product.

Patients suffering from severe renal insufficiency or renal failure must not take the product. This includes patients on dialysis.

Patients suffering from Hemochromatosis must not take this product.

4.4 Special warnings and precaution for use.

Patients suffering from renal insufficiency should consult a physician or healthcare professional prior to intake of large doses of

ascorbic acid (see section 4.9).

Health Products Regulatory Authority

10 November 2022 CRN00D61K Page 2 of 7

Do not exceed the recommended doses. Acute or chronic overdose (> 2 g / day) increases risk of adverse effects including

formation of calcium oxalate deposits, acute tubular necrosis, and/or renal failure (see section 4.9).

Patients suffering from glucose-6-phosphatase deficiency should not take higher than the recommended dose. Overdose of

vitamin C in this patient population has been associated with hemolytic anemia (see section 4.9).

Patients receiving other single vitamins or multivitamin preparations, any other medication or those under medical care must

consult a health care professional before taking this product (see section 4.5 and 4.9).

Separate the intake of the product from other medication by 4 hours unless otherwise specified (see section 4.5).

Vitamin C may interfere with laboratory tests resulting in false readings. Inform your physician when taking this product and

diagnostic measures are planned or done.

Vitamin C may interfere with test kits and meters measuring glucose levels resulting in false results. Please check the package

insert of the test kit or meter for guidance (see section 4.5).

Redoxon Double Action contains a source of phenylalanine. Therefore, may be harmful to people with phenylketonuria.

This medicinal product contains 194 mg sodium per tablet, equivalent to 9.7 % of the WHO recommended maximum daily

dietary intake of 2 g sodium for an adult. This should be taken into consideration by patients on a controlled sodium diet.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Health Products Regulatory Authority

10 November 2022 CRN00D61K Page 3 of 7

4.5 Interaction with other medicinal product and other forms of interaction.

Drug interactions:

Ascorbic Acid:

Desferrioxamine: Vitamin C may enhance tissue iron toxicity, especially in the heart, causing cardiac decompensation.

Cyclosporine: Vitamin C may reduce cyclosporine blood levels.

Warfarin: High doses of vitamin C may interfere with the effectiveness of warfarin

Zinc:

Zinc forms complexes with certain substances (including tetracycline antibiotics, quinolone antibiotics, penicillamine)

resulting in decreased absorption of both substances. As these interactions occur in the gastrointestinal tract, the potential for

interaction should be reduced by taking the product separately from other drugs. It is usually sufficient to separate the intake

by at least 2 hours before or 4-6 hours after ingestion of the other drug, unless otherwise specified.

Food interactions:

Copper:

Zinc may reduce copper absorption.

Lab interactions:

As vitamin C is a strong reducing agent, it can cause chemical interference in laboratory tests that involve oxidation-reduction

reactions, such as the analyses of glucose, creatinine, carbamazepine, uric acid, and inorganic phosphates in urine, serum and

of occult blood in feces. Refer to the manufacturer's information to determine if vitamin C interferes with the test.

4.6 Fertility, pregnancy and lactation

Pregnancy and Lactation

The product is generally considered safe during pregnancy and lactation when used as labelled. However, since there are no

sufficient controlled human studies assessing the risk of the product during pregnancy or lactation, the product should be

administered in pregnancy or lactation only when clinically indicated and considered essential by the physician.

The labelled dose should not be exceeded as chronic overdose might be harmful to the foetus and neonate.

Vitamin C and Zinc are secreted into breast milk. This must be taken into consideration if the infant is receiving any other

supplements.

Neither non-clinical nor clinical data are available to assess aspartame use in infants below 12 weeks of age.

Fertility

To date, there is no evidence suggestive that vitamin C and/or zinc causes adverse reproductive effects in humans.

4.7 Effect on the ability to drive and use machine.

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

4.8 Undesirable effect.

The listed adverse drug reactions have been identified during the post-approval use of the product. As these reactions are

reported voluntarily, a reliable estimation of their frequency is not possible.

Gastrointestinal disorders

Health Products Regulatory Authority

10 November 2022 CRN00D61K Page 4 of 7

Diarrhoea, nausea, vomiting, gastrointestinal and abdominal pain.

Immune System Disorders

Allergic reaction, anaphylactic reaction, anaphylactic shock.

Hypersensitivity reactions with respective laboratory and clinical manifestations include allergic asthma syndrome, mild to

moderate reactions potentially affecting skin, respiratory tract, gastrointestinal tract and cardiovascular system, including

symptoms such as rash, urticaria, allergic edema and angioedema, pruritus, cardio-respiratory distress, and severe reactions,

including anaphylactic shock have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued

4.9 Overdose

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

Allowance should be made for intake of vitamin C and zinc from all other sources.

Clinical signs and symptoms, laboratory findings, and consequences of overdose are highly diverse, dependent on an

individual's susceptibility and surrounding circumstances.

General manifestations of overdose with vitamin C and/or zinc may include increase of gastrointestinal disturbances including

diarrhea, nausea, and vomiting.

If such symptoms occur, the product should be stopped and a healthcare professional consulted.

Specific clinical manifestations may include the following:

Vitamin C:

Acute or chronic overdose of vitamin C may significantly elevate serum and urinary oxalate levels. In some instances, this may

lead to hyperoxaluria, calcium oxalate crystalluria, calcium oxalate deposition, kidney stone formation, tubulointerstitial

nephropathy, and acute renal failure. Individuals with mild to moderate renal insufficiency may be susceptible to these effects

of vitamin C toxicity at lower doses and should consult a health care professional before use of the product.

Overdose of vitamin C may result in oxidative hemolysis or disseminated intravascular coagulation in patients with

glucose-6-phosphate dehydrogenase deficiency.

Zinc:

Zinc overdose can cause irritation and corrosion of the gastrointestinal (GI) tract, acute renal tubular necrosis, interstitial

nephritis, copper deficiency, sideroblastic anemia, and myeloneuropathies.

If overdose with the product is suspected, intake should be stopped and a health care professional consulted for treatment of

clinical manifestations. Vitamin C is removed by hemodialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties.

ATC Code: A11GB

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.

Health Products Regulatory Authority

10 November 2022 CRN00D61K Page 5 of 7

The importance of ascorbic acid to the human body is most clearly evident in clinically 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.

5.2 Pharmacokinetic properties.

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 μ mol/l) indicate that the intake is

actually inadequate. In clinically manifest scurvy, serum concentrations are below 2 mg/l (10 μ mol/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.

5.3 Preclinical safety data.

No specific study with this product was done, but the preclinical safety of the individual components has been extensively

documented.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

S/NO	INGREDIENTS	QUANTITY/Batch (KG)
1	Gelatin	2.4 kg
2	Lactose	140kg
3	Corn starch	55.6kg
4	Methyl paraben	0.2 kg
5	Propyl paraben	0.1kg
6	Talc	2.4 kg
7	Magnesium stearate	3.6kg
8	Sodium Metabisulphite	0.3 kg
9.	Orange flavour	0.6 kg
10.	Microcrystalline Cellulose	0.2 kg

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

36 months

6.4 Special precautions for storage

Store below 25 °C.

6.5 Nature and composition of immediate packaging

1x1000 tablets containing in polypropylene cup closed by a PE

Stopper.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

No special requirements.

7.0 APPLICANT/MANUFACTURER

7.1 Name and Address

REMG PHARMACEUTICALS LIMITED

2, FOGO CLOSE, OFF OLAMBE ROAD, AKUTE, IFO L.G.A. OGUN STATE

7.2 Tel number

+234 8035596628

7.3 Email

rembrown42@yahoo.com