Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Redoxon Double Action 1000 mg/10 mg Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 effervescent tablet contains:
Ascorbic acid (vitamin C) 1000 mg
Zinc (in form of 32 mg zinc citrate trihydrate) 10 mg

Excipients:

Aspartame	15 mg
Sorbitol	655 mg
Sodium	194 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent Tablet.

Light orange round tablet with bevelled edges and flat faces.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of vitamin C and zinc deficiency.

4.2 Posology and method of administration

Adults and children over 12 years: 1 effervescent tablet a day dissolved in a glass of water (200 ml).

4.3 Contraindications

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 Nephrolitiasis 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 precautions 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).

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.

4.5 Interaction with other medicinal products 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, quinonolone antibiotics, penicillamine) resulting in decreased absorption of both substances. As these interactions occur in the gastro-intestinal 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 Effects on ability to drive and use machines

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

4.8 Undesirable effects

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

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 monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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.

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 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.

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

Sodium hydrogen carbonate
Anhydrous sodium carbonate
Anhydrous citric acid
Sorbitol (E420)
Aspartame (E951)
Acesulfame potassium
Sodium chloride
Orange flavour (acetaldehyde, ascorbic acid, ethyl butyrate, decanal, dodecanal, hexanal, orange oil, linalol, tetradecanal, nonalal, octanal, acacia and maltodextrin)
Tangerine flavour (ascorbic acid, tangerine oil, acacia and maltodextrin)
beta-carotene 1% (beta carotene crystalline, alpha tocopherol, sodium ascorbate crystalline, medium chain triglycerides, acacia, sucrose, maltodextrin and silicon dioxide)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years in plastic tubes or aluminium tubes.

1 year in aluminium foil strip.

6.4 Special precautions for storage

Store below 25 °C.

Aluminium tube and polypropylene tube:
Keep the container tightly closed, in order to protect from moisture.

Aluminium/PE strip:
Store in the original package, in order to protect from moisture.

6.5 Nature and contents of container

10, 15, 20 or 30 tablets in aluminium tube with polyester lacquer closed by a PE stopper containing a desiccant (silica gel) or in polypropylene tube closed by a PE stopper containing a desiccant (silica gel)
Box of 1 or 2 tubes containing 10 or 15 tablets

1 tablet in aluminium / PE strip

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Bayer Limited
1st Floor
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Dublin
A94 H2K7
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8 MARKETING AUTHORISATION NUMBER

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