

PROPOSED PACKAGE INSERT OF HERBIEVITE VITAMIN C CAPSULES

Western Herbal Complementary Medicine and Health Supplement.

HERBIEVITE VITAMIN C CAPSULES is unregistered and has not been evaluated by SAHPRA for its quality, safety or intended use. This medicine is not intended to diagnose, treat, cure or prevent any disease.

SCHEDULING STATUS

Not scheduled

NAME OF THE MEDICINE

HERBIEVITE VITAMIN C 500 mg CAPSULES

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Each capsule contains Vitamin C (ascorbic acid) 500 mg

PHARMACEUTICAL FORM

Capsules, HERBIEVITE VITAMIN C CAPSULES: white shaped.

CLINICAL PARTICULARS

THERAPEUTIC INDICATIONS

Vitamin C is vital for the function of the immune system and promotes resistance to infection. Vitamin C enhances iron absorption which is found primarily in fruits, vegetables, dried beans, nuts and grain products. Therefore, vitamin C can be beneficial to those with poor iron stores and do not eat adequate amounts of fresh fruits and vegetable.

Vitamin C is also a highly effective antioxidant which acts to protect cells against the effects of free radicals. Free radicals can cause cell damage that may contribute to the development of cardiovascular disease and cancers and other diseases.

Vitamin C may also be able to reactivate other antioxidants such as Vitamin E so that it can be reused.

Vitamin C is required for the production of collagen, an important structural component of blood vessels, tendons, ligaments and bone and may assist in delayed wound and bone healing

POSOLGY AND METHOD OF ADMINISTRATION

Take 1 or 2 capsules daily or as directed by your healthcare practitioner.

CONTRAINDICATIONS

Hypersensitivity to the active substance.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

- Diabetics, patients prone to recurrent renal calculi, those undergoing stool occult blood tests, and those on sodium-restricted diets or anticoagulant therapy should not take excessive doses of vitamin C over an extended period of time
- Vitamin C may interfere with tests and assays for urinary glucose, giving false-negative results with methods utilising glucose oxidase with indicator (e.g. Labstix, Tes-Tape) and false-positive results with neocuproine 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.
- Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take HERBIEVITE VITAMIN C CAPSULES.

INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION

- Ascorbic acid increases the renal excretion of amphetamine. The plasma concentration of ascorbate is decreased by smoking and oral contraceptives.
- The body breaks down estrogens to get rid of them. Vitamin C might decrease how quickly the body gets rid of estrogens. Taking vitamin C along with estrogens might increase the effects and side effects of estrogens.
- Large amounts of vitamin C might decrease how much fluphenazine (Prolixin) is in the body. Taking vitamin C along with fluphenazine (Prolixin) might decrease the effectiveness of fluphenazine (Prolixin).
- Vitamin C is an antioxidant and might decrease the effectiveness of some medications used for cancers.
- Taking large doses of vitamin C might reduce how much of some medications used for HIV/AIDS stays in the body. This could decrease the effectiveness of some medications used for HIV/AIDS. Some of these medications used for HIV/AIDS include amprenavir (Agenerase), nelfinavir (Viracept), ritonavir (Norvir), and saquinavir (Fortovase, Invirase).
- Concurrent administration of ascorbic acid with desferrioxamine enhances urinary iron excretion. Ascorbic acid should be used with caution in patients with idiopathic haemochromatosis and thalassaemias and their cardiac function should be monitored.
- Taking vitamin C, beta-carotene, selenium, and vitamin E together might decrease the effectiveness of some medications used for lowering cholesterol. Some medications used for lowering cholesterol include atorvastatin (Lipitor), fluvastatin (Lescol), lovastatin (Mevacor), and pravastatin (Pravachol).
- Taking vitamin C along with vitamin E, beta-carotene, and selenium might decrease some of the helpful effects of niacin. Niacin can increase the good cholesterol. Taking vitamin C along with these other vitamins might decrease the effectiveness of niacin for increasing good cholesterol.
- Warfarin (Coumadin) is used to slow blood clotting. Large amounts of vitamin C might decrease the effectiveness of warfarin (Coumadin). The dose of your warfarin (Coumadin) might need to be changed.
- Concomitant administration of aluminium-containing antacids may increase urinary aluminium elimination. Concurrent administration of antacids and ascorbic acid is not recommended, especially in patients with renal insufficiency.
- Co-administration with amygdalin (a complementary medicine) can cause cyanide toxicity.
- The body breaks down acetaminophen (Tylenol, others) to get rid of it. Large amounts of vitamin C can decrease how quickly the body breaks down acetaminophen.
- The body breaks down aspirin to get rid of it. Large amounts of vitamin C might decrease the breakdown of aspirin. Decreasing the breakdown of aspirin might increase the effects and side effects of aspirin. Do not take large amounts of vitamin C if you take large amounts of aspirin.
- Vitamin C is taken up by cells. Taking nifedipine (Cardene) or nifedipine (Adalat, Procardia) along with vitamin C might decrease how much vitamin C is taken in by cells.
- Vitamin C might decrease how quickly the body gets rid of salsalate (Disalcid). Taking vitamin C along with salsalate (Disalcid) might cause too much salsalate (Disalcid) in the body and increase the effects and side effects of salsalate.

FERTILITY, PREGNANCY AND LACTATION

The safety of HERBIEVITE VITAMIN C CAPSULES during pregnancy and lactation has not been established. Caution should be exercised when taking HERBIEVITE VITAMIN C CAPSULES while pregnant or breast-feeding.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

HERBIEVITE VITAMIN C CAPSULES has no effect on your ability to drive vehicles or operate machinery.

UNDESIRABLE EFFECTS

- Nervous system disorders: headache.
- Vascular disorders: flushing.
- Gastrointestinal disorders: nausea, vomiting and stomach cramps. Large doses of ascorbic acid may cause diarrhoea.
- Skin and subcutaneous tissue disorders: redness of skin.
- Renal and urinary disorders: Patients known to be at risk of hyperoxaluria should not ingest ascorbic acid doses exceeding 1g daily as there may be increased urinary oxalate excretion. Ascorbic acid has been implicated in precipitating haemolytic anaemia in certain individuals deficient of glucose-6-phosphate dehydrogenase. Increased intake of ascorbic acid over a prolonged period may result in increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly. Doses of more than 600mg daily have a diuretic effect.

REPORTING OF SUSPECTED ADVERSE REACTIONS.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to:

- SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>
- CONTEGO PHARMACEUTICALS (Pty) Ltd
250 Nadine Street, Robertville, Roodepoort, Gauteng, South Africa

OVERDOSE

Large doses of ascorbic acid may cause diarrhoea and the formation of renal oxalate calculi. Symptomatic treatment may be required.

Ascorbic acid may cause acidosis or haemolytic anaemia in certain individuals with a deficiency of glucose 6-phosphate dehydrogenase. Renal failure can occur with massive ascorbic acid overdosage.

Gastric lavage may be given if ingestion is recent otherwise general supportive measure should be employed as required.

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMIC PROPERTIES

Pharmacological classification: D 32.16 Other – Western Herbal Complementary Medicine

ATC code: A11GA01

Ascorbic acid, coupled with dehydroascorbic acid to which it is reversibly oxidised, has a variety of functions in cellular oxidation processes. Ascorbic acid is required in several important hydroxylations, including the conversion of proline to hydroxyproline (and thus collagen formation e.g. for intercellular substances and during wound healing); the formation of the neurotransmitters 5-hydroxytryptamine from tryptophan and noradrenaline from dopamine, and the biosynthesis of carnitine from lysine and methionine. Ascorbic acid appears to have an important role in metal ion metabolism, including the gastrointestinal absorption of iron and its transport between plasma and storage organs. There is evidence that ascorbic acid is required for normal leucocyte functions and that it participates in the detoxification of numerous foreign substances by the hepatic microsomal system. Deficiency of ascorbic acid leads to scurvy, which may be manifested by weakness, fatigue, dyspnoea, aching bones, perifollicular hyperkeratosis, petechia and ecchymosis, swelling and bleeding of the gums, hypochromic anaemia and other haematopoietic disorders, together with reduced resistance to infections and impaired wound healing.

PHARMACOKINETIC PROPERTIES

ABSORPTION

Ascorbic acid is well absorbed from the gastrointestinal tract.

DISTRIBUTION

Ascorbic acid is widely distributed to all tissues. Body stores of ascorbic acid normally are about 1.5g. The concentration is higher in leucocytes and platelets than in erythrocytes and plasma.

ELIMINATION

Ascorbic acid additional to the body's needs, generally amounts above 200mg daily, is rapidly eliminated; unmetabolized ascorbic acid and its inactive metabolic products are chiefly excreted in the urine. The amount of ascorbic acid excreted unchanged in the urine is dose-dependent and may be accompanied by mild diuresis.

PHARMACEUTICAL PARTICULARS

LIST OF EXCIPIENTS

Magnesium Stearate

Silicon Dioxide

INCOMPATIBILITIES

Not applicable

SHELF LIFE

3 years

SPECIAL PRECAUTIONS FOR STORAGE

Store at or below 25 °C protected from light and moisture. Keep container tightly closed.

KEEP OUT OF REACH OF CHILDREN.

NATURE AND CONTENTS OF CONTAINER

HERBIEVITE VITAMIN C CAPSULES are packed in white plastic containers with screw on cap containing 60 capsules

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

No special requirements.

HOLDER OF CERTIFICATE OF REGISTRATION

Contego Pharmaceuticals (Pty) Ltd

250 Nadine Street

Robertville, Roodepoort

Gauteng, South Africa

+27 87 150 7529

REGISTRATION NUMBER

To be allocated.

DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

To be allocated.