

CTD MODULE 1
**ADMINISTRATIVE INFORMATION AND
PRODUCT INFORMATION**

Product Name :	CHEWCEE (VITAMIN C) TABLETS (Ascorbic acid 100mg)
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1.5 Product Information: CHEWCEE (VITAMIN C) TABLETS

1.5.1 Prescribing information (Summary of products characteristics):

1. Name of the Medicinal Product: CHEWCEE (VITAMIN C) TABLETS

Strength:

Each chewable tablet contains Ascorbic acid 100mg

Pharmaceutical form: Oral Tablets

2. Qualitative and Quantitative composition:

Qualitative composition:

Sr. No.	Ingredient	Specification	Uses
1.	Ascorbic acid	BP	Active
2.	Isopropyl alcohol	BP	Solvent
3.	Sunset yellow lake	BP	Colour
4.	Maize starch	BP	Diluent
5.	Povidone K 30	BP	Disintegrant
6.	Sucrose	BP	Base
7.	Lactose	BP	Binder
8.	Di-sodium EDTA	BP	Chelator
9.	Sodium saccharine	BP	Sweetener
10.	Orange flavour powder	BP	Flavour
11.	Magnesium stearate	BP	Lubricant
12.	Ascorbic acid	BP	Active

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Quantitative composition:

Component and quality standard (and grade, if applicable)	Function	Strength (label claim)			
		Each chewable tablet contains Ascorbic acid 100mg			
		Quantity in mg per tablet	%	Quantity in Kg Per 900,000 Tablets	%
Contents of CHEWCEE TABLETS					
Ascorbic acid	Active	105.00	31.25	94.500	31.25
Isopropyl alcohol	Solvent	0.05ml	0.01	45.000L	0.01
Sunset yellow lake	Colour	0.4	0.12	0.360	0.12
Maize starch	Diluent	100.00	29.77	90.000	29.77
Povidone K 30	Disintegrant	10.00	2.98	9.000	2.98
Sucrose	Base	66.00	19.65	59.400	19.65
Lactose	Binder	40.00	11.90	36.000	11.90
Di-sodium EDTA	Chelator	6.00	1.79	5.400	1.79
Sodium saccharine	Sweetener	0.5	0.15	0.450	0.15
Orange flavour powder	Flavour	1.00	0.30	0.900	0.30
Magnesium stearate	Lubricant	7.00	2.08	6.300	2.08
Total	NA	335.95	100.00	347.31	100.00

3. Pharmaceutical form: Oral Tablets

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4. Clinical particular's:

4.1 Therapeutic indication:

Prevention and treatment of scurvy.

4.2 Posology and method of administration:

Posology

Adults and children over 6 years:

Prophylactic: 25 – 75 mg daily.

Note: This unit dosage form is unsuitable for prophylactic use.

Therapeutic: Not less than 250mg daily in divided doses. Maximum of 1000mg daily.

Children under 6 years:

This unit dosage form is unsuitable for children under 6 years.

Elderly: As for other adults. As the dietary intake of vitamin C may be less in the elderly, they have greater risk of presenting with vitamin C deficiency.

Method of administration

For oral administration.

4.3 Contraindication:

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

Ascorbic acid should not be given to patients with hyperoxaluria.

4.4 Special warning and precaution for use:

Increased intake of ascorbic acid over a prolonged period may result in an increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly (see section 4.8).

Interference with serological testing

Ascorbic acid 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 ascorbic acid may give false-negative reading in faecal occult blood tests.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interactions with other medicinal products and other forms of interactions:

Ascorbic acid increases the renal excretion of amphetamine. The plasma concentration of ascorbate is decreased by smoking and oral contraceptives.

Ascorbic acid increases the absorption of iron.

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Concomitant administration of aspirin and ascorbic acid may interfere with absorption of ascorbic acid. Renal excretion of salicylate is not affected and does not lead to reduced anti-inflammatory effects of aspirin.

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. Concurrent administration of ascorbic acid with desferrioxamine enhances urinary iron excretion. Cases of cardiomyopathy and congestive heart failure have been reported in patients with idiopathic haemochromatosis and thalassaemias receiving desferrioxamine who were subsequently given ascorbic acid. Ascorbic acid should be used with caution in these patients and cardiac function monitored.

Ascorbic acid may interfere with biochemical determinations of creatinine, uric acid and glucose in samples of blood and urine.

Additional information on special populations:

Not Applicable

Pediatric population:

Not Applicable

4.6 Fertility, pregnancy and lactation:

Pregnancy

For ascorbic acid no clinical data on exposed pregnancies are available. Animal studies do not indicate direct or harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Pregnant women should exercise caution.

Breast-feeding

Ascorbic acid is excreted in breast milk. Though again caution should be exercised, no evidence exists suggesting such excretion is hazardous to the infant.

4.7 Effects on ability to drive and use machines:

On the basis of the product's pharmacodynamic profile and reported adverse events, ascorbic acid has no known effect on an individual's ability to drive or operate machinery.

4.8 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.

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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. However, such risk has not been demonstrated in normal, non-hyper oxaluric individuals. 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 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose and Treatment:

Symptoms

At doses of over 3g per day unabsorbed ascorbic acid is mainly excreted unmetabolised in the faeces. Absorbed ascorbic acid additional to the body's needs is rapidly eliminated. 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.

Management

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

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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. Ascorbic acid is required in several important hydroxylations, including the conversion of proline to hydroxyproline (and thus in 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.

5.2 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; unmetabolised 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.

5.3 Preclinical safety data:

Not available

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6. Pharmaceutical Particulars:

6.1 List of excipients

Ascorbic acid contains the following excipients:

Isopropyl alcohol, Sunset yellow lake, Maize starch, Povidone K 30, Sucrose, Lactose, Disodium EDTA, Sodium saccharine, Orange flavour powder and Magnesium stearate.

6.2 Incompatibilities

None known

6.3 Shelf life

24 Months

6.4 Special precaution for storage

Store in a well closed container. Keep out of reach of children. Protect from light.

6.5 Nature and contents of container

Aluminium /amber PVC foil blister strip of 10x10 tablets in a unit box along with pack insert.

1000 tablets packed in polythene bag and contained in HDPE container with leaflet.

6.6 Special precautions for disposal

No special precaution

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7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES:

Marketing Authorization Holder:

Rene Industries Ltd

Address: PO Box 6034, Plot No.680, Kamuli, Kireka, Kampala, Uganda.

Manufactured by:

Rene Industries Ltd

Address: PO Box 6034, Plot No.680, Kamuli, Kireka, Kampala, Uganda.

8. MARKETING AUTHORISATION NUMBER:

Not Applicable

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION:

Not Applicable

10. DATE OF REVISION OF THE TEXT:

Not Applicable

11. DOSIMETRY (IF APPLICABLE):

Not Applicable

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE):

Not Applicable