For the use of a Registered Medical Practitioner only

1. GENERIC NAME AND BRAND NAME

Vitamin C Chewable Tablets 500 mg
LIMCEE®

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated chewable tablet contains:
Ascorbic Acid IP……..100 mg
Sodium Ascorbate IP……450 mg
equivalent to Ascorbic acid….400 mg
Excipients……...q.s.
Colour: Sunset Yellow FCF

3. DOSAGE FORM AND STRENGTH

Kindly refer to section 1 & 2

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATION

Vitamin C is recommended for the prevention and treatment of scurvy. Symptoms of mild deficiency may include faulty bone, gingivitis, bleeding gums, and loosened teeth.

Febrile states, chronic illness and infection increase the need for ascorbic acid (vitamin C) and may predispose a patient to other Vitamin C deficiency states.

Vitamin C is an antioxidant and helps to reduce free radical damage to the body cells.

Maintains and supports collagen formation.

Vitamin C also helps maintain immune system health and boosts immunity.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Method of Administration

Vitamin C tablets should be taken orally. Vitamin C chewable tablets are to be chewed completely before swallowing.

Children > 12 years and Adults: 1 tablet per day or as directed by the Physician
Children < 12 years: Under Medical Supervision

Table 1: Tolerable Upper Intake Levels (ULs) for Vitamin C

Age	Male	Female	Pregnancy	Lactation
0–12 months	Not possible to establish*	Not possible to establish*		
1–3 years	400 mg	400 mg		
4–8 years	650 mg	650 mg		
9–13 years	1,200 mg	1,200 mg		
14–18 years	1,800 mg	1,800 mg	1,800 mg	1,800 mg
19+ years	2,000 mg	2,000 mg	2,000 mg	2,000 mg

4.3 CONTRAINDICATIONS

- Hypersensitivity to any component of this preparation.
- Oxalate urolithiasis and iron storage diseases (thalassaemia, haemochromatosis, sideroblastic anaemia) or other medical conditions that predispose individuals to iron overload.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Special Warnings

Exceeding the recommended dose should be avoided as there have been isolated reports of severe haemolysis in patients with erythrocytic glucose-6-phosphate dehydrogenase deficiency when taking high doses (> 4000 mg/day) of ascorbic acid. Do not exceed the recommended dose.

Caution is required and use the minimum recommended dose in patients with renal impairment.

Patients with rare hereditary fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase deficiency should not take ascorbic acid.

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.

Keep out of reach of children.

Precautions for use

- Diabetics taking more than 500 mg vitamin C daily may obtain false readings of their urinary glucose test.
- No exogenous vitamin C should be ingested for 48 to 72 hours before amine-dependent stool occult blood tests are conducted because possible false-negative results may occur.

4.5 DRUG INTERACTIONS

Ascorbic acid (Vitamin C)

Administration of ascorbic acid leads to increased absorption of iron from the gastrointestinal tract. This should be borne in mind in the case of iron replacement.

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. In early treatment, when there is excess tissue iron, there is some evidence that ascorbic acid may worsen iron toxicity, particularly to the heart. Ascorbic acid should be used with caution in these patients and cardiac function monitored.

Ascorbic acid may increase gastrointestinal absorption of aluminium. Concomitant administration of aluminium-containing antacids may affect urinary aluminium elimination. Concurrent administration of antacids and ascorbic acid is not recommended, especially in patients with renal insufficiency.

Concomitant administration of acetylsalicylic acid (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.

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

Co-administration with amygdalin (a complementary medicine) can cause cyanide toxicity.
Ascorbic acid may interfere with biochemical determinations of creatinine, uric acid and glucose in samples of blood and urine.

Cyclosporine: Vitamin C may reduce cyclosporine blood levels.
Warfarin: High doses of Vitamin C may interfere with the effectiveness of warfarin.
Indinavir: High dose of Vitamin C significantly reduces the serum concentration of indinavir, which may interfere with the effectiveness of Indinavir.
Disulfiram: Chronic or high doses of Vitamin C may interfere with the effectiveness of disulfiram.

4.6 USE IN SPECIAL POPULATIONS (SUCH AS PREGNANT WOMEN, LACTATING WOMEN, PAEDIATRIC PATIENTS, GERIATRIC PATIENTS ETC.)

Pregnancy

Category C

- It is also not known whether Vitamin C can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.
- Vitamin C should therefore be given to a pregnant woman only if clearly needed.

Nursing Mothers

- Caution should be exercised when vitamin c is given to a nursing woman.

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

- Diarrhea, nausea, vomiting, abdominal cramps/pain, or heartburn

- Painful urination, pink/bloody urine.
- A very serious allergic reaction to this drug is rare which if occurs causes rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

4.9 OVERDOSAGE

Occasionally transient osmotic diarrhea may occur in doses over 2 g and almost always at doses above 10 g.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 MECHANISM OF ACTION

Ascorbic acid is an electron donor (reducing agent or antioxidant), and probably all of its biochemical and molecular functions can be accounted for by this function.

5.2 PHARMACODYNAMICPROPERTIES

Due to its redox potential ascorbic acid acts as a co-factor of numerous enzyme systems (collagen formation, catecholamine synthesis, hydroxylation of steroids, tyrosine and exogenous substances, biosynthesis of carnitine, regeneration of tetra hydro-folic acid and alpha amidation of peptides, e.g. ACTH and gastrin). In addition ascorbic acid deficiency impairs the immune defence reactions, especially chemotaxis, complement activation and interferon production. The molecular biological functions of ascorbic acid have not been fully elucidated.

Ascorbic acid improves the absorption of iron salts by reducing ferric ions and forming iron chelates. It blocks the chain reactions triggered by oxygen radicals in aqueous compartments of the body. The antioxidative functions form a close biochemical interaction with those of vitamin E, vitamin A and carotenoids.

Data from clinical trials suggests the role of Vitamin C in immune cells. Leukocytes, such as neutrophils and monocytes, actively accumulate Vitamin C against a concentration gradient, resulting in values that are 50- to 100-fold higher than plasma concentrations. These cells accumulate maximal Vitamin C concentrations at dietary intakes of ~100 mg/day, although other body tissues likely require higher intakes for saturation. Accumulation of millimolar concentrations of Vitamin C into neutrophils, particularly following activation of their oxidative burst, is thought to protect these cells from oxidative damage. Vitamin C is a potent water-soluble antioxidant that can scavenge numerous reactive oxidants and can also regenerate the important cellular and membrane antioxidants glutathione and vitamin E. Upon phagocytosis or activation with soluble stimulants, Vitamin C is depleted from neutrophils in an oxidant-dependent manner. Vitamin C has been shown to attenuate both oxidant generation and NFkB activation in dendritic cells in vitro. Thiol-containing proteins can be particularly sensitive to redox alterations within cells and are often central to the regulation of redox-related cell signalling pathways. Vitamin C -dependent modulation of thiol-dependent cell signalling and gene expression pathways has been reported in T-cells. Thus, Vitamin C can modulate immune function through modulation of redox-sensitive cell signalling pathways or by directly protecting important cell structural components. In patients with inadequate vitamin C status (i.e., <50 μM), supplementation with vitamin C (providing ~250 mg/day) resulted in a 20% increase in neutrophil chemotaxis, thus contributing to improved immune function. In clinical studies high doses of vitamin C not only stimulated murine immune cells, primarily dendritic cells, to more distinct interleukin (IL)-12 secretion, but also activated T and B cell functions.

In studies in healthy subjects, administration of vitamin C resulted in improvement of several components of human immune parameters, such as antimicrobial and natural killer cell activities, lymphocyte proliferation, chemotaxis, and delayed type hypersensitivity response.

Intracellular concentrations of vitamin C in human leukocytes have been shown to decline with increasing age, accompanied by neutrophil function impairment. Oral administration of vitamin C results in improved neutrophil functions and serum immunoglobulin levels. Investigations show that administration of 1 g of vitamin C (together with 200 mg of vitamin E) for 16 weeks to healthy elderly women enhanced neutrophil chemotaxis and phagocytosis, and decreased concentrations in serum lipid peroxides, which is indicative of improved resistance to oxidative stress

5.3 PHARMACOKINETICS PROPERTIES

Absorption
Ascorbic acid is absorbed in the proximal small intestine in a concentration-dependent manner. As the unit dose increases the bioavailability falls to 60-75% after 1 g, to approximately 40% after 3 g and down to 16% after 12 g. The unabsorbed proportion is broken down by the flora in the large intestine, predominantly to CO2 and organic acids.

Metabolism
In healthy adults the maximum metabolic turnover of 40 to 50 mg/day is achieved at plasma concentrations of 0.8 to 1.0 mg/dl. The total daily turnover is about 1 mg/kg. At extremely high oral doses plasma concentrations of up to 4.2 mg/dl are achieved for a short time after about 3 hours.

Elimination
Ascorbic acid is excreted in the urine more than 80% unchanged. The mean half-life is 2.9 hours. Renal excretion takes place by glomerular filtration followed by reabsorption in the proximal tubule. Upper limit concentrations in healthy adults are 1.34 ± 0.21 mg ascorbic acid/dl in men and 1.46 ± 0.22 mg ascorbic acid/dl plasma in women.

The total body content of ascorbic acid after high intake of about 180 mg a day is at least 2g. Ascorbic acid accumulates in the pituitary gland, adrenal glands, lenses of the eyes and white blood cells.

Data from Clinical Trials
Meta-analysis has indicated that vitamin C supplementation with doses of 200 mg or more daily is effective in ameliorating the severity and duration of the common cold, and the incidence of the common cold if also exposed to physical stress.[1]

A randomised double-blind trial involving vitamin C/placebo supplementation was conducted on 57 elderly patients admitted to hospital with acute respiratory infections (bronchitis and bronchopneumonia). Patients were assessed clinically and biochemically on admission and again at 2 and 4 weeks after admission having received either 200 mg vitamin C per day, or placebo. At the end of the 4 weeks period, there was 50% more improvement in the total respiratory score which corelated with the significantly higher plasma and white cell concentration of Vitamin C in the test group.[2]

In a meta-analysis comprising of twenty-nine trials involving 11,306 participants, regular intake of vitamin C resulted in lower incidence of common cold. In adults the duration of colds was reduced by 8% (3% to 12%) and in children by 14% (7% to 21%). In children, 1 to 2 g/day vitamin C shortened colds by 18%. The severity of colds was also reduced by regular vitamin C administration.[3]

In a randomised control trial, 140 patients diagnosed with acute pneumonia were admitted in the hospital. In patients given low-dose vitamin C (0.25–0.8 g/day) the hospital stay reduced by 19% compared with no vitamin C supplementation, whereas in the higher-dose group (0.5–1.6 g/day) the duration of hospital stay reduced by 36%. There was also a positive effect on the normalization of chest X-ray, temperature, and erythrocyte sedimentation rate.[4]

In a double-blind, 5-year randomized controlled trial, 244 patients were evaluated to study the effects of low dose (50mg) and high dose (500mg) supplementation of Vitamin C on frequency and duration of common cold. The incidence of cold was higher (9.2%) in the low dose group and was lower (3.2%) in the high dose group. Total number of common colds (per 1000 person-months) during the supplementation was 21.3 for the low-dose group and 17.1 for the high-dose group. Among the 113 subjects in the low-dose and 115 in the high dose group, 25 (25.7 %) and 20 (17.4 %), respectively,
reported having caught cold during the previous year (P= 0.13). The adjusted total severity score was 4.3 for the low-dose group and 4.2 for high-dose group (P = 0.91).[5]

6. NONCLINICAL PROPERTIES

6.1 ANIMAL TOXICOLOGY OR PHARMACOLOGY

The requirement of ascorbic acid for the induction by polychlorinated biphenyls (PCB) of hepatic drug-metabolizing enzymes in ODS-od/od rat (OD rat) which is a rat mutant unable to synthesize ascorbic acid. ODS- +/+ rats (+/+ rat), which can synthesize ascorbic acid, were used as controls. In OD rats, the dietary requirement of ascorbic acid to maintain normal growth and prevent any signs of scurvy is about 300 mg of ascorbic acid per kilogram diet.

7. DESCRIPTION

Light orange coloured, round, flat bevel edged tablets scored on one side, with slight mottling and having a characteristic odour.

8. PHARMACEUTICAL PARTICULARS

8.1 INCOMPATIBILITIES

Not Applicable

8.2 SHELF-LIFE

Refer Pack

8.3 PACKAGING INFORMATION

Refer Pack

8.4 STORAGE AND HANDING INSTRUCTIONS

Refer Pack

9. PATIENT COUNSELLING INFORMATION

Limcee 500 contain Vitamin C in the form of Ascorbic Acid. Vitamin C is needed to maintain immune system health and for boosting immunity. It is a potent antioxidant that helps to reduce free radical damage to the body cells. It is also needed to maintain and support collagen formation, which is required for healthy skin, bones, vessels, cartilage etc. Febrile states, chronic illness, and infections increase the need of ascorbic acid (vitamin c) and may predispose a patient to Vitamin C deficiency states. Vitamin C is recommended for the prevention and treatment of scurvy. Symptoms of mild deficiency may include faulty bone, gingivitis, bleeding gums, and loosened teeth.

Advise the patients to avoid taking Limcee 500 if:

- They are allergic to Ascorbic Acid or any of the other ingredients of this medicine.
- They suffer from hyperoxaluria (excretion of urine containing large amounts of calcium oxalate crystals).

Advise the patients to talk to their doctor before taking Limcee 500 Tablets:

1) If they are to undergo any blood or urine tests as ascorbic acid can interfere with some blood and urine tests.

2) If they have kidney failure as ascorbic acid enhances aluminium absorption (present in antacids) which may reach toxic levels. Stop taking this medicine immediately and consult the doctor if an allergic reaction occurs after taking this medicine. An allergic reaction may include itching, a rash, swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing.

10. DETAILS OF MANUFACTURER

MANUFACTURED BY:

Refer Pack for manufacturer details

11. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE

Refer Pack for Permission/License details

12. DATE OF REVISION

Version 4.0 Dated 05/02/2025

For Product Complaints/Adverse events or Queries please write to **webmasterindia@abbott.com**

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References:

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