



Brand Name : AGO C-500	2021
Generic Name : Ascorbic Acid Tablets BP 500 mg	
Module 1 Administrative Information and Product Information	Confidential
1.5 Product Information	

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

AGO C - 500 (Ascorbic Acid Tablets BP 500 mg)

2. Qualitative and Quantitative Composition:

Each chewable tablet contains: Ascorbic Acid BP 500 mg

3. Pharmaceutical form:

An orange coloured spotted round shape chewable tablets having a break line on one side of each tablet.

4. Clinical particulars:

4.1 Therapeutic Indications:

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 Contraindications:

- 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 Warnings and Precautions 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may result in an increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly (see section 4.8).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 readings 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 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.

4.6 Overdose:

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.

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 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.



6. **Pharmaceutical particulars:**

6.1 **List of Excipients:**

Aspartame	IP
Sucrose	IP
Ethyl Cellulose	BP
Iso Propyl Alcohol	IP
Methyl Paraben Sodium	IP
Propyl Paraben Sodium	IP
Colour Sunset Yellow Lake	INH
Talcum	IP
Essence Orange Powder	INH
Magnesium Stearate	IP

6.2 **Incompatibilities:**

None Reported

6.3 **Shelf-Life:**

36 months from the date of manufacture.

6.4 **Special Precautions for Storage:**

Store in a cool, dry and dark place. Protect from light.

6.5 **Nature and Contents of Container:**

10 tablets packed in one strip. Such 10 strip packed in unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper.

1000 tablets packed in one jar. Such jar packed in export worthy shipper.

6.6 **Special precautions for disposal:**

None reported.

7. **Registrant:**

AGOG PHARMA LTD.

Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraiпада,
Vasai (E), Dist. Thane, India.

8. **Manufacturer:**

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India.

9. **Date of revision of the text:**