

Package Leaflet: Information for the patient

C-Vital 500 mg

Chewable Tablets

Vitamin C (Ascorbic Acid)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take C-Vital 500 mg chewable tablets
3. How to take C-Vital 500 mg chewable tablets
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1. What C-Vital 500 mg chewable tablets is and what it is used for

Therapeutic Indications

C-Vital chewable tablets are indicated for the prevention and treatment of ascorbic acid (Vitamin C) deficiency if sufficient supply from the diet is not ensured.

2. What you need to know before you take C-Vital 500 mg chewable tablets

Contraindications

C-Vital chewable tablets are contraindicated in:

- Hypersensitivity to the active ingredient or any of the other constituents.
- Oxalate urolithiasis and iron storage diseases (thalassaemia, haemochromatosis, sideroblastic anaemia) or other medical conditions that predispose individuals to iron overload.

Special Warnings and Special Precautions for Use

Exceeding lets 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.

Keep out of sight and reach of children.

Interaction with Other Medicaments and Other Forms of Interaction

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 deferoxamine enhances urinary iron excretion.

Cases of cardiomyopathy and congestive heart failure have been reported in patients with idiopathic haemochromatosis and thalassaemias receiving deferoxamine 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 may increase gastrointestinal absorption of aluminum. Concomitant administration of aluminum-containing antacids may affect urinary aluminum elimination. Concurrent administration of antacids and ascorbic acid is not recommended, especially in patients with renal insufficiency.

Concomitant administration of acetylsalicylic acid 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.

Pregnancy and Lactation

It is recommended not to exceed the stated doses during pregnancy and lactation. Ascorbic acid is excreted in breast milk and crosses the placenta.

A safe upper intake level (UL) recommended for ascorbic acid is 1800 mg/day (Pregnancy or lactation; <18 years) and 2000 mg/day (Pregnancy or lactation; >18 years).

Effects on Ability to Drive and Use Machines

No impairment known.

Special Patient Populations

Large doses of ascorbic acid are reported to result in haemolysis in patients with G6PD deficiency.

3. How to take C-Vital 500 mg chewable tablets

Posology and Method of Administration

Method of Administration

C-Vital chewable tablets are to be chewed before swallowing.

Adults and Children ≥ 13 years

1-2 tablets per day (equivalent to 500 or 1000 mg/day) until symptoms abate.

Children 6-12 years

1 tablet per day (equivalent to 500 mg/day) until symptoms abate.

A longer duration of treatment may be required in the case of ascorbic acid deficiency. Reevaluate treatment if use is planned for more than 6 months.

These formulations are not recommended for use in children under 6 years.

Renal Impairment

Caution is required in patients with renal impairment (see Special Warnings and Special Precautions for Use).

Overdose

Occasionally transient osmotic diarrhoea may occur in doses over 3 g and almost always at doses above 10 g.

There is a risk of haemolysis and kidney stones being formed if high doses of ascorbic acid are taken.

4. Possible side effects

Adverse reactions reported from post-marketing experience are tabulated below by System Organ Class and frequency. The following convention has been utilised for the classification of undesirable effects: very common ($\geq 1/10$), common ($\geq 1/100$, $< 1/10$), uncommon ($\geq 1/1,000$, $< 1/100$), rare ($\geq 1/10,000$, $< 1/1000$), very rare ($< 1/10,000$), not known (cannot be estimated from available data).

Immune system disorders

Very rare

Allergic reactions, including hypersensitivity reactions (such as shortness of breath, swelling of the face and skin rash).

Nervous system disorders

Very rare

Headache and dizziness.

Gastrointestinal disorders:

Very rare

Nausea, vomiting, diarrhoea, dyspepsia and abdominal pain.

General disorders and administration site conditions

Very rare

Fatigue.

5. How to store C-Vital 500 mg chewable

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What C-Vital 500 mg chewable tablets contain:

The active substance is Vitamin C (Ascorbic acid). Each tablet contains 166.7 mg Ascorbic Acid and 375 mg Sodium Ascorbate (equivalent to 333.3 mg of Ascorbic Acid).

The other ingredients are: Mannitol, Sucralose, Microcrystalline cellulose, Colloidal silica anhydrous, Magnesium stearate, FD&C yellow 5, Orange flavor.

What C-Vital 500 mg chewable tablets look like and contents of the pack

C-Vital 500 mg chewable tablets are pale yellow to yellow round tablets.

C-Vital 500 mg chewable tablets is available in carton box containing 30 tablets (3 blisters, 10 tablets per each).

Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l. – Lebanon

P.O. Box 90201 Jdeidet-El-Metn, Lebanon

Contact us: pharmaline@maliagroup.com

Company website: www.pharmaline.com.lb

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