For the use only of Registered Medical Practitioners or a Hospital or a Laboratory

CELIN TABLETS 500 mg / CELIN CHEWABLE TABLETS

Vitamin C Tablets IP 500 mg / Vitamin C Chewable Tablets

QUALITATIVE AND QUANTITATIVE COMPOSITION

CELIN TABLETS:

Each uncoated tablet contains:
Vitamin C IP 500 mg
Excipients q.s.

CELIN CHEWABLE TABLETS :

Each uncoated chewable tablet cotains:
Ascorbic Acid IP 200 mg
Sodium Ascorbate IP 338 mg (equivalent to 300 mg of Ascorbic Acid)
Excipients q.s.
Colour : Sunset Yellow Lake

PHARMACEUTICAL FORM

Uncoated tablets; Uncoated Chewable tablets.

CLINICAL PARTICULARS

Therapeutic Indications

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

Posology and Method of Administration

Method of Administration

CELIN tablets should be taken orally. *CELIN* 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. Revaluate 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*).

Contraindications

CELIN / CELIN 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 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 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 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.

Undesirable 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 (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥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.

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.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

ATC Code: A11GA01.

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.

Pharmacodynamic Effects

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 tetrahydrofolic acid and alpha-amidation of peptides, e.g. ACTH and gastrin). In addition a 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.

Pharmacokinetic 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 CO_2 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 1.5 g. Ascorbic acid accumulates in the pituitary gland, adrenal glands, lenses of the eyes and white blood cells.

Special Patient Populations

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

Preclinical Safety Data

Preclinical safety data on ascorbic acid obtained from the literature and in-house have not revealed findings which are of relevance to the recommended dosage and use of the product

Higher concentrations of ascorbic acid interfere with several clinical chemical determination methods (glucose, uric acid, creatinine, an organic phosphate). These concentrations can be reached with gram doses in urine. Also the detection of occult blood can show false-negative results. In general chemical detection methods based on colour reactions can be influenced.

PHARMACEUTICAL PARTICULARS

List of Excipients

CELIN TABLETS:

Starch, Tartaric acid, Colloidal Silicon Dioxide, Magnesium Stearate, Starch Maize

CELIN CHEWABLE TABLETS:

Sucrose, Tartaric Acid, Colour Sunset Yellow Lake, Saccharin, Magnesium Stearate, Flavour Trusil Orange Sp., Flavour Trusil Pineapple Sp.

Incompatibilities

No incompatibilities have been identified.

Shelf Life

The expiry date is indicated on the label and packaging.

Special Precautions for Storage

Store at a temperature below 30^0 C, protected from light and moisture.

Avoid contact with metals.

Keep out of reach of children.

Nature and Specification of Container

Strips of tablets in a carton.

Instructions for Use / Handling

CELIN TABLETS / *CELIN CHEWABLE TABLETS* may darken slightly on keeping but their medicinal value remains unchanged.

There are no special requirements for use or handling of this product.

For further information please contact:
GlaxoSmithKline Pharmaceuticals Limited.
Registered Office:
Dr. Annie Besant Road, Worli
Mumbai 400 030, India.

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Version: CEL/PI/IN/2018/01 dated 22 Aug 2018

Adapted from Ascorbic Acid (Consumer) GDS version 01 dated 11 November 2014.