

## 1. Name of the medicinal product

Em-vit C Chewable 100mg

## 2. Qualitative and quantitative composition

### Em-vit100 Chewable tablets:

Each tablet contains 100 mg Em-vit c.

For the full list of excipients, see section 6.1.

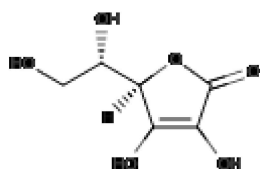
## 3. Pharmaceutical form

Orange colored tablet.

### Em-vit C 100 mg film-coated tablets:

Orange coloured, round shaped (diameter is --- mm), tablets with break line on one side and plain on the other side. The tablet can be divided into equal doses.

## Structure



## Chemical formular

$C_6H_8O_6$

## 4. Clinical particulars

### 4.1 Therapeutic indications

**Em-vit C** is a vitamin used to correct vitamin C deficiency and to increase the intestinal absorption of iron.

Also used to treat scurvy, delayed wound and bone healing, urine acidification, and in general as an antioxidant. It has also been suggested to be an effective antiviral agent.

### 4.2 Posology and method of administration.

The tablet should be chewed thoroughly and swallowed with a glass of water preferably after a meal. It is recommended, that patients with a sensitive stomach take Em-vit C during a meal.

## RDA

Males: 90 mg/day

Females: 75 mg/day

Pregnant: 85 mg/day; not to exceed 2000 mg/day (80 mg if <18 years; not to exceed 1800 mg/day)

Nursing: 120 mg/day; not to exceed 2000 mg/day (115 mg if <18 years old; not to exceed 1800 mg/day)

### **Urinary Acidification**

4-12 g/day PO/IV divided three or four times daily

### **Ascorbic Acid Deficiency (Scurvy)**

Oral prevention: See recommended daily intake

Oral treatment: 250 mg PO QID x 1 week

### **Dosing Consideration**

Use with caution in patients with renal impairment (see section 4.3)

#### **Limitations of use**

- Ascor is not indicated for treatment of vitamin C deficiency that is not associated with signs and symptoms of scurvy

## **4.3 Contraindications**

Hypersensitivity

#### **Cautions**

Hemolysis has been reported with Em-vit c in patients with glucose-6-phosphate dehydrogenase deficiency; discontinue treatment if hemolysis is suspected and treat as needed

Em-vit c may interfere with laboratory tests based on oxidation-reduction reactions (eg, blood and urine glucose testing, nitrite and bilirubin levels, and leucocyte count testing); delay laboratory tests until 24 hours after ascorbic acid infusion if possible

#### ***Oxalate nephropathy and nephrolithiasis***

- Acute and chronic oxalate nephropathy reported with prolonged administration of high doses of ascorbic acid
- Increased risk for oxalate nephropathy in patients with renal disease, renal impairment, history of oxalate kidney stones, and geriatric patients
- Monitor renal function; discontinue treatment if oxalate nephropathy develops and treat any suspected oxalate nephropathy accordingly

#### ***Drug interactions overview***

- Ascorbic acid may decrease effects of erythromycin, kanamycin, streptomycin, doxycycline, and lincomycin; if antibiotic efficacy is suspected, discontinue ascorbic acid
- Limited case reports have suggested interference of ascorbic acid with anticoagulation effects of warfarin; monitor
- **Amphetamine and other drugs affected by urine pH**

Ascorbic acid may acidify urine

Lowers amphetamines levels by increasing renal excretion

May alter excretion of certain drugs affected by urine pH (eg, fluphenazine)

#### 4.4 Pregnancy & Lactation

##### Pregnancy

No adverse developmental outcomes are reported in the published literature

There are no available data on use of Em-vit c in pregnant women to inform a drug-associated risk of adverse developmental outcomes

##### Lactation

There are no data on the presence of Em-vit c in human milk following IV dosing in lactating women

Em-vit c is present in human milk after maternal oral intake

#### 4.5 Interaction with other medicinal products and other forms of interaction

***Concomitant use of Em-vit c and the following substances should be avoided:***

<u>Aluminum hydroxide</u>	Em-vit C can cause an increase in the absorption of Aluminum hydroxide resulting in an increased serum concentration and potentially a worsening of adverse effects.
<u>Amphetamine</u>	The serum concentration of Amphetamine can be decreased when it is combined with Em-vit C.
<u>Benzphetamine</u>	The serum concentration of Benzphetamine can be decreased when it is combined with Em-vit C.
<u>Bleomycin</u>	The therapeutic efficacy of Bleomycin can be decreased when used in combination with Em-vit C.
<u>Bortezomib</u>	The therapeutic efficacy of Bortezomib can be decreased when used in combination with Em-vit C.
<u>Chlorpropamide</u>	Em-vit C may decrease the excretion rate of Chlorpropamide which could result in a higher serum level.
<u>Conjugated estrogens</u>	The serum concentration of Em-vit C can be decreased when it is combined with Conjugated estrogens.
<u>Cyclosporine</u>	The serum concentration of Cyclosporine can be decreased when it is combined with Em-vit C.
<u>Deferoxamine</u>	The risk or severity of Cardiovascular Impairment can be increased when Em-vit C is combined with Deferoxamine.
<u>Dextroamphetamine</u>	The serum concentration of Dextroamphetamine can be decreased when it is combined with Em-vit C.

#### Food Interactions

Avoid multivalent ions. Do not infuse with elemental compounds that can be reduced, such as copper.

#### **4.8 Undesirable effects**

##### **Frequency Not Defined**

Flushing  
Flank pain  
Faintness, headache  
Diarrhea, dyspepsia, nausea, vomiting  
Hyperoxaluria (large doses)

### **5. Pharmacological properties**

#### **5.1 Pharmacodynamics**

Em-vit C (vitamin C) is a water-soluble vitamin indicated for the prevention and treatment of scurvy, as ascorbic acid deficiency results in scurvy. Collagenous structures are primarily affected, and lesions develop in bones and blood vessels. Administration of ascorbic acid completely reverses the symptoms of ascorbic acid deficiency.

#### **5.2 Mechanism of Action**

In humans, an exogenous source of ascorbic acid is required for collagen formation and tissue repair by acting as a cofactor in the posttranslational formation of 4-hydroxyproline in -Xaa-Pro-Gly- sequences in collagens and other proteins. Em-vit C is reversibly oxidized to dehydroascorbic acid in the body. These two forms of the vitamin are believed to be important in oxidation-reduction reactions. The vitamin is involved in tyrosine metabolism, conversion of folic acid to folinic acid, carbohydrate metabolism, synthesis of lipids and proteins, iron metabolism, resistance to infections, and cellular respiration.

#### **5.3 Metabolism**

Hepatic (Em-vit C) Ascorbic acid is reversibly oxidised (by removal of the hydrogen from the enediol group of ascorbic acid) to dehydroascorbic acid. The two forms found in body fluids are physiologically active. Some ascorbic acid is metabolized to inactive compounds including ascorbic acid-2-sulfate and oxalic acid.

### **6. Pharmaceutical particulars**

#### **6.1 List of excipients**

- *Sucrose (table sugar)*
- *Mannitol*

- *Stevia*
- *Natural fruit flavors (e.g., orange, berry, citrus)*
- *Artificial flavors*
- *Food-grade colorants (e.g., FD&C Yellow #6, FD&C Red #40)*
- *Microcrystalline cellulose*
- *Polyvinylpyrrolidone (PVP)*
- *Cross-linked sodium carboxymethylcellulose (croscarmellose sodium)*
- *Cross-linked polyvinylpyrrolidone*
- *Silicon dioxide*
- *Magnesium stearate*
- *Calcium carbonate*
- *Ascorbic acid (Vitamin C itself can act as a preservative)*
- *Food-grade waxes*

## **6.2 Incompatibilities**

Heat, Moisture and Oxidation.

## **6.3 Shelf life**

3 years

## **6.4 Special precautions for storage**

This medicinal product does not require any special storage conditions.

## **6.5 Nature and contents of container**

Em-vit C tablets are packaged in clear PVC– Aluminum foil blister pack.

Pack sizes:

Blisters: tablets.

Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal and other handling**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## **7. Marketing Authorisation holder**

**Emzor Pharmaceutical Industries Limited**

**Km 1 Flowergate Mixed Development Scheme,**

**Sagamu/Benin Expressway, Makun, Sagamu, Ogun-State**

## **8. Marketing Authorisation number(s)**

04-4053