



**Biomedical Limited,
1, Ohimege Road, Industrial Estate, Ga-Imam, Ilorin, Kwara State**

Summary of Product Characteristics

Doc No. BML/VCD/S001

Date rev. 05/2022

Next rev date: 04/2027

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For

Biomedical Vitamin C Drop

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1. Name of Medicinal Product

Name, strength, concentration of drug product:

Vitamin C, 100mg/1ml

Each 1ml contains:

Vitamin C 100mg

Pharmaceutical Dosage Form:

Oral Liquid (drop)

2. Qualitative and Quantitative Composition

Vitamin C; 100mg/1ml

Each 1ml contains:

Vitamin C; 100mg

Excipient with Known Effect

There is no excipient with known effect

3. Pharmaceutical Form

Light yellow coloured syrup packed in amber coloured PET bottle

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4. Clinical Particulars

4.1 Therapeutic indications

Prevention and treatment of scurvy.

4.2 Posology and method of administration

As dietary supplement

Neonates: 0 – 2 months 0.2ml daily

Infants: 2 months – 1 year 0.3ml daily

1- 2 years 0.3ml – 0.6ml daily

For treatment of scurvy

Neonates: 0 – 2 months 0.4 daily

Infants: 2 months – 1 year 0.6ml daily

Or as directed by the physician.

4.3 Contraindications

Hypersensitivity to the ingredient

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may result in an increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly (see section 4.8).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 reading in faecal occult blood tests.

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Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose m

4.5 Interaction with other medicinal products and other forms of interaction

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

Ascorbic acid increases the absorption of iron.

Concomitant administration of 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.

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

Co-administration with amygdalin (a complementary medicine) can cause cyanide toxicity.

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. Ascorbic acid should be used with caution in these patients and cardiac function monitored.

Ascorbic acid may interfere with biochemical determinations of creatinine, uric acid and glucose in samples of blood and urine.


4.6 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.

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4.7 Undesirable effects

Nervous system disorders: headache.

Vascular disorders: flushing.

Gastrointestinal disorders: nausea, vomiting and stomach cramps. Large doses of ascorbic acid may cause diarrhoea.

Skin and subcutaneous tissue disorders: redness of skin.

Renal and urinary disorders: Patients known to be at risk of hyperoxaluria should not ingest ascorbic acid doses exceeding 1g daily as there may be increased urinary oxalate excretion. However, such risk has not been demonstrated in normal, non-hyper oxaluric individuals. Ascorbic acid has been implicated in precipitating haemolytic anaemia in certain individuals deficient of glucose-6-phosphate dehydrogenase.


Increased intake of ascorbic acid over a prolonged period may result in increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly. Doses of more than 600mg daily have a diuretic effect.

4.8 Overdose

Symptoms

At doses of over 3g per day unabsorbed ascorbic acid is mainly excreted un - metabolised 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.

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Management

Gastric lavage may be given if ingestion is recent otherwise general supportive measure should be employed as required.

5. PHARMACOLOGICAL PROPERTIES

Pharmacodynamics

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 in 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.

Pharmacokinetics

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.

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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

Sucrose
Methyl hydroxyl paraben
Riboflavin
Sodium benzoate
Citric acid anhydrous
Sweet orange flavor
Lemon flavor
Propylene glycol
Glycerol
Sodium metabisulfite

6.2 Incompatibilities

none

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store in temperature not more than 30°C.

Replace cap after use and store away from light.

6.5 Nature and contents of container

100ml pack size Coloured plastic bottle

7. Marketing Authorization Holder

Biomedical Limited