Professional Information

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

BE-TABS ASCORBIC ACID 500 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Ascorbic acid 500 mg

Sugar Free

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet

White to off-white round tablet with a score on the one side.

500 mg tablet: 12,8 mm in diameter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Vitamin C is indicated for the treatment of ascorbic acid deficiency, especially frank scurvy.

4.2 Posology and method of administration

Posology

Treatment for deficiency: oral, 500 mg two times a day after meals, maximum daily dose of 1000 mg.

Method of administration

For oral administration.

4.3 Contraindications

- **BE-TABS ASCORBIC ACID 500 mg** is contraindicated in patients with a known hypersensitivity to the active substance, ascorbic acid or to any of the excipients listed in **section 6.1,**
- Ascorbic acid should be given with care to patients with hyperoxaluria.

4.4 Special warnings and precautions for use

Tolerance may be induced in patients taking high doses.

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period may result in increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly. (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, Testape) and false-positive results with neocuproin 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.

4.5 Interaction with other medicines 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 Fertility, 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.

4.7 Effects on ability to drive and use machines

On the basis of the product's pharmacodynamic profile and reported adverse events, ascorbic acid has no known effect on an individual's ability to drive or operate machinery.

4.8 Undesirable effects

System Organ Class	**Frequency Unknown**
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 1 g daily as there may be increased urinary oxalate excretion. However, such risk has not been demonstrated in normal, non-hyper oxaluric individuals. 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. Ascorbic acid has been implicated in precipitating haemolytic anaemia in certain individuals deficient of glucose-6-phosphate dehydrogenase.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care provders are asked to report any suspected adverse reactions to SAHPRA via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

Symptoms

At doses of over 3 g 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 dyhydrogenase. Renal failure can occur with massive ascorbic acid overdosage.

Management

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A.22.1.4 Vitamins, other.

ATC Code of Ascorbic Acid : A11G A01

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 carnatine 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

hyperkeratoses, petechia and ecchymosis, swelling and bleeding of the gums, hypochromic anaemia and other haematopoietic disorders, together with reduced residence to infections and impaired would healing.

5.2 Pharmacokinetic properties

Ascorbic acid is well absorbed from the gastro-intestinal tract, and is widely distributed to all tissues. Body stores of ascorbic acid normally are about 1,5 g. The concentration is higher in leucocytes and platelets than in erythrocytes and plasma. Ascorbic acid additional to the body's needs, generally amounts above 200 mg 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

- Colloidal silicone dioxide
- Magnesium stearate
- Microcrystalline cellulose
- Purified talc

6.2 Incompatibilities

None known

6.3 Shelf life

24 Months – 28, 100, 500, 1000 and 5000 tablets.

15 Months – Patient ready packs of different pack sizes.

6.4 Special precautions for storage

Store in a cool dry place at or below 25 ^{o}C.

Store out of direct sunlight

6.5 Nature and contents of container

500 mg tablet: 28, 100, 500, 1000 and 5000. Patient ready packs of different pack sizes

6.6 Special precautions for disposal and other handling

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

Return all unused or expired medicines to your pharmacist for safe disposal. Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

7. HOLDER OF CERTIFICATE OF REGISTRATION

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill Ext.1

Roodepoort, 1724

South Africa

8. REGISTRATION NUMBER(S)

T1211 (Act 101/1965). (SA: 500 mg).

Botswana List number: B9314940 (Botswana 500 mg)

NS0 14/22.1.4/0553 (Namibia)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

September 1985

10. DATE OF REVISON OF THE TEXT

16 September 2022