Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Haliborange Vitamin C 500mg Effervescent Tablets (Orange Flavour)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains 500mg ascorbic acid.

Excipients: Each Effervescent Tablet contains Sorbitol (E420) and 325.78 mg of Sodium.

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Effervescent Tablet.
Round, unvaulted, speckled, reddish effervescent tablet with an orange flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Prophylaxis and treatment of ascorbic acid deficiency.

4.2 Posology and method of administration

Adults and children over 12 years: One tablet to be taken daily.

DO NOT EXCEED THE STATED DOSE

Method of Administration

The tablet to be dissolved in water (minimum 150 ml) before swallowing.

4.3 Contraindications

Ascorbic acid in doses greater than 1 g daily should not be given to patients with hyperoxaluria.

4.4 Special warnings and precautions for use

This medicinal product contains 325.78 mg of sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

Because of the sorbitol (E420) content of this product, patients with rare hereditary problems of fructose intolerance should not take this medicine.

Because of the sorbitol (E420) content of this product, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Side effects including nausea, vomiting, abdominal cramping, headaches have been reported.

Large doses of ascorbic acid may cause diarrhoea.

Patients known to be at risk of hyperoxaluria should not ingest ascorbic acid in doses in excess of 1 g daily as there may be increased urinary oxalate excretion.

Ascorbic acid has caused haemolytic anaemia in certain individuals with a deficiency of glucose-6-phosphate dehydrogenase.

Increased intake of ascorbic acid over a prolonged period may result in an increase in renal clearance of ascorbic acid and deficiency may result if it is withdrawn rapidly.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent administration of ascorbic acid and fluphenazine reportedly resulted in decreased fluphenazine plasma concentration.

4.6 Fertility, pregnancy and lactation

Ascorbic acid in doses greater than 1g daily should not be taken during pregnancy since the effect of large doses on the foetus is unknown. Ascorbic acid crosses the placenta and is distributed into breast milk.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None applicable.

4.9 Overdose

Symptoms of overdosage are unlikely following a single acute intake of this product, as ascorbic acid in excess of the body's needs is rapidly eliminated into urine. Drinking large amounts of water will also help to deplete excess ascorbic acid.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ascorbic acid functions as a co-factor in a number of hydroxylation and amidation reactions by transferring electrons to enzymes that provide reducing equivalents.

5.2 Pharmacokinetic properties

Ascorbic acid is readily absorbed from the gastrointestinal tract and is widely distributed in the body tissues.

Ascorbic acid is reversibly oxidised to dehydroascorbic acid; some is metabolised to ascorbate-2-sulphate, which is inactive, and oxalic acid which is excreted in the urine.

Ascorbic acid in excess of the body's need is also rapidly eliminated in the urine.

5.3 Preclinical safety data

There are no preclinical data of relevance which are additional to those already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric Acid Anhydrous
Sodium Hydrogen Carbonate
Inulin
Sodium Cyclamate
Maize Starch
Orange flavour 54.206
Orange flavour 860.786 (containing sorbitol (E420))
Saccharin Sodium
Beetroot powder
Riboflavin Sodium Phosphate
Modified Potato Starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Store below 25°C. Keep in the original container tightly closed.

6.5 Nature and contents of container

Polypropylene tube with polyethylene stopper (filled with desicating material) containing 10 or 20 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Seven Seas Limited,
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8 MARKETING AUTHORISATION NUMBER

PA 417/16/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th December 1992
Date of last renewal: 18th December 2007

10 DATE OF REVISION OF THE TEXT

January 2011