

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Redoxon C, Chewable Tablets 500mg Orange Flavour

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ascorbic Acid and Sodium Ascorbate equivalent to ascorbic acid 500mg/tablet.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Chewable Tablets

Cylindrical, bi-planar, mottled pinkish orange chewable tablet with bevelled edges, imprinted 'REDOXON' on obverse and C/500 on reverse, with odour and flavour of oranges.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As specific replacement therapy for scurvy.

As an adjunct in the management of nutritional deficiency and such conditions as wound healing and infections.

4.2 Posology and method of administration

Tablets to be taken orally, according to the following dosage schedules.

Adults: One to three tablets daily or as directed by the physician.

Children, Infants and Neonates: As recommended by the physician.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

Large doses of ascorbic acid may cause diarrhoea.

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a prolonged period may result in an increase in renal clearance of ascorbic acid, and deficiency may result if it is withdrawn rapidly.

- Contains a source of phenylalanine
- Contains sorbitol
- Unsuitable in hereditary fructose intolerance.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 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.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

No side effects have been reported at the recommended dosage.

4.9 Overdose

Large doses of ascorbic acid may cause diarrhoea.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ascorbic Acid (Vitamin C) is a water-soluble vitamin which is oxidised to dehydroascorbic acid. Both ascorbic acid and dehydroascorbic acid participate in oxidation and reduction processes. Exogenous ascorbic acid is required for collagen formation and tissue repair.

5.2 Pharmacokinetic properties

After oral administration ascorbic acid is well absorbed from the intestine. At doses of over 3g per day absorption is saturated and ascorbic acid is chiefly excreted unmetabolised in the faeces. Ascorbic acid additional to the body's needs is rapidly eliminated; unmetabolised vitamin C and its inactive metabolic products are chiefly excreted in the urine. The amount of ascorbic acid excreted unchanged in the urine is dose-dependant.

5.3 Preclinical safety data

No additional information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol (E420)
Purified talc
Magnesium stearate
Yellow iron oxide (E172)
Red iron oxide (E172)
Aspartame (E951)
Orange flavour

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container.

6.5 Nature and contents of container

The tablets are filled into amber glass bottles fitted with lined aluminium screw caps. The bottles are packed into cardboard cartons.

Pack size: 50 tablets.

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

Bayer Plc
Bayer House
Strawberry Hill
Newbury
Berkshire
RG14 1JA
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 21/72/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 June 1984

Date of last renewal: 28 June 2004

10 DATE OF REVISION OF THE TEXT

October 2005