Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Redoxon Plain Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ascorbic acid 1000 mg.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent Tablets
White to slightly yellow cylindrical, bi-planar uncoated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Prevention and treatment of scurvy, and as an adjunct in the treatment of wounds and fractures, infections and anaemia.

4.2 Posology and method of adminstration

Tablets to be dissolved in water and taken orally, according to the following dosage schedules.

Adults:
Scurvy - 0.5 g to 1 g two to three times daily.
Infections, wound healing - 0.5 g to 1 g two to three times daily.
Other indications include supplementation when requirements are increased - 50mg to 200 mg daily.

Children:
Over 12 years - Three quarters adult dose.
4-12 years - Half adult dose.
Under 4 years - One quarter adult dose.

4.3 Contraindications

None.

4.4 Special warnings and precautions for use

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

Ascorbic acid may cause haemolytic anaemia in persons with glucose 6 phosphate dehydrogenase deficiency.

4.5 Interaction with other medicinal products and other forms of interaction

Ascorbic acid should be avoided by diabetic patients using urinary glucose testing methods since urinary vitamin C may interfere with such tests.

4.6 Pregnancy and lactation

Ascorbic acid in doses greater than 1 g 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

Side effects do not occur under normal conditions of use.

4.9 Overdose

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a prolonged period may result in an increase in renal clearance of ascorbic acid, and deficiency may result if it is withdrawn rapidly.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Vitamin C is required in several important hydroxylations; the formation of 5-hydroxytryptamine and noradrenaline; and the biosynthesis of carnitine. Vitamin C appears to have an important role in metal ion metabolism and there is evidence that it is required for normal leukocyte function and that it participates in the detoxification of numerous foreign substances.

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-dependent.

5.3 Preclinical safety data

No additional information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Tartaric acid
Sodium hydrogen carbonate
Blood orange flavour
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. Keep the container tightly closed.

6.5 Nature and contents of container

The tablets are over wrapped in an aluminium foil laminate and packed into polypropylene or aluminium tubes. The tubes may be packed into cardboard cartons.

Pack sizes 10, 20 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 21/74/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1 April 1983

Date of last renewal: 1 April 2003

10 DATE OF REVISION OF THE TEXT

October 2005