

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Redoxon Effervescent Tablets 1000 mg Orange.

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ascorbic Acid 1000 mg

##### *Excipients*

Aspartane	15	mg
Sorbitol	655	mg
Sodium	194	mg

For a full list of excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Effervescent Tablets.

Round, flat pale orange coloured tablets.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

As specific replacement treatment of 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 dissolved in water and taken orally, according to the following dosage schedules

###### *Adults*

1 to 3 tablets daily.

###### *Elderly persons*

No special dosage regimen is required.

###### *Children (4 to 12 years)*

Half a tablet twice daily or as recommended by a doctor.

##### 4.3 Contraindications

None known.

#### 4.4 Special warnings and precautions for use

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a prolonged period may result in an increase in renal clearance of ascorbic acid, and deficiency may result if it is withdrawn rapidly.

This medicinal product contains 194 mg sodium per tablet. To be taken into consideration by patients on a controlled sodium diet.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

#### 4.5 Interaction with other medicinal products and other forms of interaction

Oral contraceptives reduce the levels of vitamin C in the body by means of oxidation, presumably via a raised ceruloplasmin level.

Corticosteroids enhance oxidation.

Calcitonin increases the rate at which vitamin C is utilised.

Salicylates inhibit active transport through intestinal wall.

Tetracycline inhibits intracellular metabolism and re-absorption from the renal tubules.

Acetylsalicylic acid, barbiturates and tetracycline increase the excretion of vitamin C in the urine.

In diabetics, high doses of ascorbic acid may interfere with tests for urinary glucose, although it has no effect on blood sugar levels. The administration of vitamin C should therefore be stopped several days before such tests are performed.

Ascorbic acid interferes with screening tests for paracetamol in urine based upon hydrolysis and formation of an indophenol blue chromogen, causing negative screening tests to occur in the presence of acetaminophen.

Ascorbic acid may result in false negative guaiac tests (greater than 1 g daily) and ascorbic acid should be discontinued if an interference with this guaiac test is suspected.

At high doses (more than 2g/day) vitamin C may interfere with the following biological tests: plasmatic and urinary concentration of creatinine as well as with tests for occult bleeding in stool.

#### 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.

Regular users who wish to discontinue use of the product during pregnancy and lactation should gradually reduce their intake as vitamin C deficiency may occur if the product is withdrawn rapidly.

#### 4.7 Effects on ability to drive and use machines

None.

## 4.8 Undesirable effects

The listed adverse drug reactions are based on spontaneous reports, thus a ranking under the headings of frequency is not pertinent.

### *Blood and lymphatic system disorders*

Vitamin C may cause haemolytic anemia in certain individuals with a deficiency of glucose-6-phosphate dehydrogenase.

### *Gastrointestinal disorders*

Diarrhoea, nausea, vomiting, abdominal pain

### *Skin and subcutaneous tissue disorders*

Pruritus, rash, urticaria (may also be signs of allergic reactions).

### *Immune System Disorders*

Allergic reaction, anaphylactic reaction, anaphylactic reaction, anaphylactic shock.

Hypersensitivity reactions with respective laboratory and clinical manifestations include asthma syndrome, mild to moderate reactions potentially affecting skin, respiratory tract, gastrointestinal tract, and cardiovascular system, including symptoms such as rash, urticaria, oedema, pruritus, throat-swelling, cardio-respiratory distress, and very rarely, severe reactions, including anaphylactic shock have been reported.

## 4.9 Overdose

Single cases of acute and chronic overdoses are reported in the literature. Ascorbic acid overdose may result in oxidative haemolysis in patients with glucose-6-phosphate dehydrogenase deficiency, disseminated intravascular coagulation, and calcium oxalate crystalluria in patients who have a predisposition for increased crystal aggregation, tubulointerstitial nephropathy, and acute renal failure as a result of calcium oxalate crystals.

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 noradrenalin; 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-dependant.

### 5.3 Preclinical safety data

No additional information.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium Hydrogen Carbonate  
Anhydrous Sodium Carbonate  
Anhydrous Citric Acid  
Sorbitol (E420)  
Aspartame (E951)  
Acesulfame Potassium  
Sodium Chloride  
Orange flavour  
Tangerine flavour  
Beta-carotene

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf Life**

3 years.

### **6.4 Special precautions for storage**

Do not store above 25°C. Keep the container tightly closed.

### **6.5 Nature and contents of container**

Polypropylene tubes of 10, 15 or 20 tablets with a polythene cap containing 2.1g of desiccant.

Aluminium tubes of 10, 15 or 20 tablets with a polythene cap containing 2.1g of desiccant.

One or two tubes are packed in cardboard cartons to contain 10, 15, 20 or 30 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**

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

Trading as Bayer plc, Consumer Care Division.

**8 MARKETING AUTHORISATION NUMBER**

PA 0021/074/004

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 30<sup>th</sup> June 1976

Date of last renewal: 30<sup>th</sup> June 2006

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