BIORAJ PHARMACEUTICALS LIMITED	
BRAND NAME: Bioracee Tablet (Coloured)	Ascorbic Acid BP.…….100mg
SUMMARY OF PRODUCT CHARACTERISTICS	

1. NAME OF THE MEDICINAL PRODUCT

Bioracee Tablet (Coloured)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ascorbic Acid BP.…….100mg

3. PHARMACEUTICAL FORM

Oral solid.

An orange circular tablet with BPL on one side and break line on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutics indications

Bioracee is used in the prevention and treatment of Vitamin C deficiency. Bioracee is used for prevention and treatment of scurvy.It assists in the healing of wounds and prevention of body infection. Bioracee is essential for the maintenance of good health in infants and children

4.2 Posology and method of administration

For Oral use.

Bioracee contains Ascorbic Acid (Vitamin C) – a water soluble vitamin, which is essential for the maintenance of healthy growth.Deficiency in the intake of Vitamin C leads to scurvy which is characterized by capillary fragility and bleeding (especially from the gum), anaemia, cartilage/bone lesion and slow healing of wounds.

Method of administration

*Adults and children and above 10 years:*Two tablets 3 times daily.

4.3 Contraindications

Bioracee syrup should not be used in**,** oxalate-urolithiasis and iron storage diseases (thalassaemia, haemochromatosis, sideroblasticanaemia).

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Care should be taken in giving Bioracee to patient with hyperoxaluria as this may alter the excretion of certain other drugs administered concurrently.

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a prolonged period may result in an increase in renal clearance of ascorbic acid and deficiency may result, if it is withdrawn.

For patients with extreme or terminal renal insufficiency (patients of dialysis), respectively, a daily vitamin-C-uptake of 50 to 100 mg of vitamin C should not be exceeded, because otherwise, there is the risk of hyperoxalataemia and crystallisations of oxalate in the kidneys.

High dose vitamin C therapy should be avoided in patients with underlying renal insufficiency or urinary oxalate should be monitored in patients. Nephrotoxic symptoms can occur in patients with renal failure and patients who concomitantly use medicinal products with negative effect on the renal function, e.g. iron overload due to enhanced iron reabsorption.

This medicinal product contains 321 mg sodium per dose and has to be taken carefully in hypertensive patients.

4.5 Interaction with other medicinal products and other forms of interaction

Corticosteroids increase the oxidation of ascorbic acid. Calcitonin increases the rate of vitamin C consumption. Salicylates inhibit active transportation through the intestine. Tetracyclines inhibit intracellular metabolism and reabsorption from the renal tubes. Acetylsalicylic acid, barbiturates and tetracyclines increase vitamin C excretion in the urine.

Several cases have been reported, in which ascorbic acid appeared to reduce the effect of warfarin.

Ascorbic acid can decrease the therapeutic effect of phenothiazines.

The concentration of fluphenazine may also be reduced.

High doses of vitamin C taken together with iron may cause an iron overload due to enhanced iron reabsorption.

High doses of vitamin C taken together with aluminium may cause increased aluminium reabsorption.

Chronic use of high doses of ascorbic acid may interfere with disulfiram – alcohol interaction when used concurrently.

Alcohol reduces ascorbic acid levels.

4.6 Fertility, pregnancy and lactation

Pregnancy

It is not advisable to exceed the given dosage during pregnancy and lactation**.**

There is limited amount of data from the use of high dose vitamin C in pregnant women. It is not clear if vitamin C supplementation in amounts exceeding Dietary Reference Intake recommendations is safe or beneficial.

Breastfeeding

Ascorbic acid is secreted into breast milk and crosses the placental barrier by means of simple diffusion. There is insufficient information on the effects of high dose vitamin C in newborns/ infants. It is not clear if vitamin C supplementation in amounts exceeding Dietary Reference Intake recommendations is safe or beneficial.

Fertility

The effect of large doses on the fetus is not known.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Respiratory and cutaneous hypersensitivity reactions have been observed in isolated cases.

4.9 Overdose

Bioracee (Vitamin C) is usually well tolerated. Large doses are reported to cause diarrhoea and other gastro-intestinal disturbance and are associated with the formation of renal calcium oxalate calculi. Patients with recurring formation of renal calculi are recommended not to exceed a daily vitamin-C-uptake of 100 to 200 mg.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ascorbic acid (vitamin C), ATC-Code: A11GA01

Vitamin C is essential to humans. Its components, ascorbic acid andehydroascorbic acid, form an important redox system.

Vitamin C acts as a cofactor in numerous enzyme systems due to its redox potential (collagen formation, catecholamine synthesis, hydroxylation of steroids, tyrosine and exogenous substances, biosynthesis of carnitin, regeneration of tetrahydrofolic acid and alpha-amidisation of peptides, e.g. ACTH and gastrin).

Further, a deficiency of vitamin C affects the immune defence reactions, particularly chemotaxis, complement activation and interferon production. The molecular biological functions of vitamin C have not yet been fully explained.

Ascorbic acid improves the re-absorption of iron salts by reducing ferric ions and by forming iron chelates. It blocks the chain reactions in aqueous body compartments triggered by oxygen radicals.

The antioxidative functions produce biochemical interactions in close relation to those of vitamin E, vitamin A and carotinoids. As yet it has not been proven entirely that ascorbic acid causes a reduction of potentially carcinogenic substances in the gastrointestinal tract.

5.2 Pharmacokinetic properties

Ascorbic acid is absorbed in the proximal small intestine in a dose-dependent manner. The bioavailability drops with increasing dosage to 60 - 75% after 1 g, to approx. 40% after 3 g and approx. 16% after 12 g. The portion which is not absorbed is broken down by the large intestinal flora into CO_2 and organic acids.

The maximal metabolic turnover of 40 to 50 mg/day in healthy adults is reached at plasma concentrations of 0.8 to 1.0 mg/dl. The total daily turnover is about 1 mg/kg BW. Brief plasma concentrations of up to 4.2 mg/dl are achieved about three hours after applying extremely high oral doses.

Under these circumstances ascorbic acid is eliminated in the urine by up to 80%. The half-life constitutes 2.9 hours on average. Renal elimination ensues via glomerular filtration and subsequent reabsorption in the proximal tubule. The

upper limits given for healthy adults are 1.34 ± 0.21 mg ascorbic acid/dl plasma in men and 1.46 ± 0.22 mg in women, respectively.

The total body content of ascorbic acid is at least 1.5 g following a high dose of about 180 mg daily. Ascorbic acid is concentrated in the pituitary gland, adrenal glands, lenses of the eye and white blood cells.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of single and repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Maize starch
- Methyl paraben
- Propyl paraben
- Carmosine red
- Gelatin
- Tartrazine Yellow
- Aspartame
- Manesium stearate
- Purified Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30 °C. Keep away from sunlight.

6.5 Nature and contents of container

CC container

Pack size: 1000

6.6 Special precautions for disposal and other handling

None applicable

7. MARKETING AUTHORISATION HOLDER

Bioraj Pharmaceuticals Limited

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