SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ESOCEE Syrups (Ascorbic acid Oral Solution 100 mg/ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Vitamin C (Ascorbic acid) BP…..100 mg

3. PHARMACEUTICAL FORM

Oral Solution
A pale Yellow and viscous syrup with pleasant orange taste.

4. CLINICAL PARTICULARS

Therapeutic indications

Esocee Syrups is used in the prevention and treatment of Vitamin C deficiency. It is used for the prevention and treatment of Scurvy. It enhances resistance to infections especially

after surgery. Vitamin C is essential for the development of cartilage, bone and teeth for the healing of wounds. Vitamin C is essential for the maintenance of good health in infants and children. **Posology and method of administration** For oral administration only.

Syrups	**Dietary Supplementary (daily)**	**Treatment of Scurvy (4 times a daily)**
Neonates (up to 2 months)	0.2 ml (20 mg)	0.4 ml (40 mg)
Infants (2months-1 year)	0.3 ml (30 mg)	0.6 ml (60 mg)
Children (1-2 yrs)	0.3 ml-0.6 ml (30 mg-60 mg)	0.6 ml-1 ml (60 mg-100 mg)
Children (3 – 5yrs)	1-3 (5 ml) teaspoonful three times daily or as directed by the physician	100mg

Contraindications:

Vitamin C should not be used in, oxalate-urolithiasis and iron storage diseases (thalassaemia, haemochromatosis, sideroblastic anaemia). Hypersensitivity to the active substance or to any of the excipients mentined below.

Special warnings and precautions for use:

Due to the intake of high doses of vitamin C (4 g per day) by patients with an erythrocytic glucose-6-phosphate dehydrogenase deficiency, partly serious haemolyses have been observed in single cases. Therefore, exceeding the given dosing recommendations must be avoided. 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a prolonged period may result in an increase in renal clearance of ascorbic acid and deficiency may result, if it is withdrawn. In case of the susceptibility to renal calculi, there is the risk of the formation of calcium oxalate calculi due to the intake of high doses of vitamin C. Patients with recurring formation of renal calculi are recommended not to exceed a daily vitamin-C-uptake of 100 to 200 mg. 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 an enhanced iron reabsorption. See section 4.5. This medicinal product

contains 321 mg sodium per dose and has to be taken carefully in patients following salt restricted diet (e. g. hypertensive patients). The administration of gram doses can elevate the ascorbic acid concentration in the urine to such a degree that the measurement of various clinical-chemical parameters (glucose, uric acid, creatinine, inorganic phosphate) is impaired. Likewise, gram doses can lead to false-negative results in the attempted detection of occult blood in the stools. Generally, chemical detection methods which are based on colour reactions can be affected. The colourings contained in Dr. Scheffler Vitamin C - orange yellow S (E 110) and azorubine (E 122) - can cause allergic reactions, including asthma. Such allergic reactions can occur in particular in persons allergic to acetylsalicylic acid This medicinal product contains sorbitol and therefore patients with rare hereditary problems of fructose intolerance should not take this medicine. Paediatric population This strength is not recommended for children (below 18 years).

Interaction with other medicinal products and other forms of interaction Although the following interactions between vitamin C and other drugs have been described, their relevance at the proposed dosage is not documented: Vitamin C in a dosage of 1 g daily increases the bioavailability of oral contraceptives (oestrogens). 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 an enhanced iron reabsorption. High doses of vitamin C taken together with aluminium may cause increased aluminium reabsorption. Cyclosporine A bioavailability can be decreased by vitamin C. One case has been reported, in which the risk of cyanide toxicity has been increased by co-ingestion of mega doses of vitamin C and amygdalin. Chronic use of high doses of ascorbic acid may interfere with disulfiram – alcohol interaction when used concurrently. Alcohol reduces ascorbic acid levels.

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.

Effects on ability to drive and use machines

None known.

Undesirable effects

Respiratory and cutaneous hypersensitivity reactions have been observed in isolated cases. Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via.

Overdose

See “Warnings” regarding the risk of renal calculi and haemolyses, respectively. Temporary osmotic diarrhoea occasionally occurs after single doses of 3 g, and almost always after more than 10 g, accompanied by respective abdominal symptoms.

5. PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Ascorbic acid (vitamin C), ATC-Code: A11GA01 Vitamin C is essential to humans. Its components, ascorbic acid and dehydroascorbic 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 resorption 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.

Pharmacokinetic properties

Ascorbic acid is absorbed in the proximal small intestine in a dose-dependent manner. The bioavailability Syrups 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 CO2 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.

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

List of excipients

Glycerin

Sorbitol

Incompatibilities

None

Shelf life

3 years

Special precautions for storage

Store in cool & dry place, below 30°C.

Nature and contents of container

100 ml Amber Glass Bottle

7. APPLICANT/MANUFACTURER

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