CISPEY

INSTRUCTIONS FOR THE MEDICINAL PRODUCT

Trade name: Cispey.
International nonproprietary name: Ascorbic acid.
Dosage form: Film-coated tablets.
Composition: each film coated tablet contains:
Active substance:
10 mg natural Vitamin C from Rose Hip extract and Vitamin C (Ascorbic acid) up to 1000 mg.
Excipients: Cellactose, Copovidone, Croscarmellose sodium, Magnesium stearate, Hypromellose, Macrogol 6000, Talk.
Pharmacotherapeutic group: Vitamins.
ATCClassification**:** A11GA01.
Pharmacologic property:
Pharmacodynamics:
Ascorbic acid, coupled with dehydroascorbic acid to which it is reversibly oxidised, has a variety of functions in cellular oxidation processes. Ascorbic acid is required in several important hydroxylations, including the conversion of proline to hydroxyproline (and thus in collagen formation e.g. for intercellular substances and during wound healing); the formation of the neurotransmitters 5-hydroxytryptamine from tryptophan and noradrenaline from dopamine, and the biosynthesis of carnitine from lysine and methionine.
Ascorbic acid appears to have an important role in metal ion metabolism, including the gastrointestinal absorption of iron and its transport between plasma and storage organs. There is evidence that ascorbic acid is required for normal leucocyte functions and that it participates in the detoxification of numerous foreign substances by the hepatic microsomal system. Deficiency of ascorbic acid leads to scurvy, which may be manifested by weakness, fatigue, dyspnoea, aching bones, perifollicular hyperkeratoses, petechiae and ecchymoses, swelling and bleeding of the gums, hypochromic anaemia and other haematopoietic disorders, together with reduced residence to infections and impaired would healing.
Pharmacokinetics:
Ascorbic acid is well absorbed from the gastro-intestinal tract, and is widely distributed to all tissues. Body stores of ascorbic acid normally are about 1.5g. The concentration is higher in leucocytes and platelets than in erythrocytes and plasma. Ascorbic acid additional to the body's needs, generally amounts above 200mg daily, is rapidly eliminated; unmetabolised ascorbic acid and its inactive metabolic products are chiefly excreted in the urine. The amount of ascorbic acid excreted unchanged in the urine is dose-dependent and may be accompanied by mild diuresis.
Indications for use:
- Vitamin C deficiency.
- Treatment and prevention of scurvy.

Contra-indications:
- Hypersensitivity to ascorbic acid or some of the excipients of medicine;
- Hypercoagulability;
- Thrombophlebitis;
- Thrombotic tendency;
- Diabetes mellitus;
- Children's age (14 years);
- Nephrolithiasis
- Hyperoxaluria.

Precautions: renal insufficiency hemochromatosis, thalassemia, polycythemia, leukemia, sideroblastic anemia, deficiency of glucose-6-phosphate dehydrogenase, sickle cell anemia, progressive malignant disease.
Pregnancy and Nursing Mother:
For ascorbic acid no clinical data on exposed pregnancies are available.
Pregnant women should exercise caution.
Ascorbic acid is excreted in breast milk. Though again caution should be exercised, no evidence exists suggesting such excretion is hazardous to the infant.

Dosage and directions for use:
The recommended dose is 1 film coated tablet of 1000 mg daily.
In some cases (significant hypovitaminosis C) can be taken up to 2 film coated tablets daily.
The dosage form is not suitable for pediatric patients.
Side-effects:
Gastrointestinal disturbances: nausea, vomiting and stomach cramps.
Large doses of ascorbic acid may cause diarrhoea.
Flushing or redness of skin, headache.
Patients known to be at risk of hyperoxaluria should not ingest ascorbic acid doses exceeding 1gm daily, as there may be increased urinary oxalate excretion. However, such risk has not been demonstrated in normal, non-hyper oxaluric individuals. Ascorbic acid has been implicated in precipitating haemolytic anaemia in certain individuals deficient of glucose-6-phosphate dehydrogenase.
Increased intake of ascorbic acid over a prolonged period may result in increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly. Doses of more than 600mg daily have a diuretic effect.
Overdose:
At doses of over 3mg per day unabsorbed ascorbic acid is mainly excreted unmetabolised in the faeces. Absorbed ascorbic acid additional to the body's needs is
rapidly eliminated. Large doses of ascorbic acid may cause diarrhoea and the formation of renal oxalate calculi. Symptomatic treatment may be required.
Drug interaction:
Ascorbic acid increases the renal excretion of amphetamine. The plasma concentration of ascorbate is decreased by smoking and oral contraceptives.
Ascorbic acid increases the absorption of iron.
In renal failure, oral vitamin C enhances aluminium absorption, which may reach toxic levels.
Co-administration of aluminium hydroxide and ascorbic acid may promote increased
aluminium absorption in patients with normal renal function.
Co-administration with amygdalin (a complementary medicine) can cause cyanide toxicity.
Ascorbic acid is often given in addition to desferrioxamine to patients with iron overload to achieve better iron excretion. However, early on in treatment when there is excess tissue iron there is some evidence that ascorbic acid may worsen the iron toxicity, particularly to the heart. Thus, ascorbic acid should not be given for the first month after starting desferrioxamine treatment.
Cautions:
Increased intake of ascorbic acid over a prolonged period may result in increased renal clearance of ascorbic acid, and deficiency may result if the intake is reduced or withdrawn rapidly.
Ascorbic acid may interfere with tests and assays for urinary glucose, giving false-negative results with methods utilising glucose oxidase with indicator and falsepositive results with neocuproin methods. Estimation of uric acid by phosphotungstate or uricase with copper reduction and measurement of creatine in non-deproteinised serum may also be affected. High doses of ascorbic acid may give false-negative readings in faecal occult blood tests.
Cispey contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Effects on ability to drive and use machines:
Has no known effect on an individual's ability to drive or operate machinery.
Presentation:

Box with 30 film coated tablets of 1000 mg in plastic container with

instruction for use.

Storage:

Keep in dry place, protected from light at a temperature below

25°C.
Keep out of reach of children.
Shelf life:
Labeled. Do not use after expiry date.
Distribution Condition:

Non-prescribed medicine.

SPEY
The holder of Trade Mark and Marketing Authorization is:
SPEY MEDICAL
England, UK
Manufactured by:
REPLEK FARM Ltd. Skopje
R. Macedonia