

21.04.2021 TEK BAŞINA ASKORBIK ASIT (C VİTAMİNİ) İÇEREN PARENTERAL PREPARATLAR
HK_ENG

MINISTRY OF HEALTH OF THE REPUBLIC OF TURKEY Medicines and Medical Devices Agency
of Turkey

Number : E-62820468-000-411377 Subject : Parenteral Preparations Containing "Ascorbic Acid (Vitamin C)" NORMAL

21.04.2021 DOSSIER

You may find below the decision adopted in consequence to the evaluation made by the "Clinical Evaluation Unit" on parenteral preparations containing "Ascorbic acid (Vitamin C)" alone:
- Parenteral preparations containing ascorbic acid alone with a dose-volume higher than 5 ml to be administered at once will have a "hospital product" status. - Parenteral products containing ascorbic acid alone will have a "prescription-only medicine" status. - The relevant sections of the Summary of Product Characteristics and Patient Leaflet of registered products or products for which registration application will be submitted should be modified as follows.

4.1 Therapeutic indications It is in the following cases: - In case of severe vitamin C (Ascorbic acid) deficiency, - For compensating or preventing vitamin C deficiency where oral use is insufficient, is not feasible, or is contraindicated.

4.2. Posology and mode of administration Posology/frequency and duration of use: Dose for adults: It may be administered maximum up to 10 days at a dose of 500-1000 mg/day in severe vitamin C deficiency. It may be administered at a dose of 200-500 mg/day for compensating or preventing vitamin C where oral administration is not sufficient, is not feasible or is contraindicated.

Dose for children: A dose of 100-300 mg/day may be administered once or twice daily from 2 weeks to 3 months depending on the improvement of symptoms for the treatment of severe vitamin C deficiency. Parenteral vitamin C may be used in parenterally fed preterm infants in whom oral administration is not feasible and in infants aged between 0-12 months at a dose of 15-25 mg/kg/day and a dose of 80 mg/day in children aged between 1-18 years. No special dose recommendation is needed for the elderly.

Mode of administration: It is administered intramuscularly or intravenously. Intramuscular administration is preferred. It should be infused slowly in intravenous administration. Rapid intravenous injection may cause transient dizziness.

Additional information on special populations: Renal impairment: It should be used carefully.

Liver failure: No special dose recommendation is needed.

Pediatric Population: Parenteral vitamin C may be used in parenterally fed preterm infants in whom oral administration is not feasible and in infants aged between 0-12 months at a dose of 15-25 mg/kg/day and a dose of 80 mg/day in children aged between 1-18 years.

Geriatric population: No special dose recommendation is needed.

4.3. Contraindications It should not be used in individuals known to develop hypersensitivity reactions against ascorbic acid and the substances contained. It should not be used in case of hyperoxaluria.

4.4. Special warnings and precautions for use Oxalate nephropathy, nephrolithiasis, and renal impairment. Prolonged use of high-dose vitamin C may lead to oxalate nephropathy. Risk of formation of oxalate calculi increased in the administration of vitamin C in renal impairment, nephrolithiasis, in the elderly and infants aged below 2 years. Vitamin C treatment should be discontinued in patients in whom oxalate calculi are formed. Renal functions of all patients who receive vitamin C treatment should be monitored.

G6PD Deficiency High-dose vitamin C should be used carefully in patients with G6PD deficiency as it may lead to hemolysis.

Hemochromatosis Desferrioxamine should be used carefully as it may increase side effects and toxicity.

Laboratory Test Interference It may lead to false-positive and negative results in the glucose measurements made by using glucose oxidase and copper sulfate, the determination of nitrite and bilirubin, and leukocyte count.

I hereby submit for your information and kindly request that any views, proposals, and remarks on the decision adopted are submitted to the Clinical Evaluation Unit within 5 days as of the date of publication of this association decision, that no application is made to the Clinical Evaluation Unit except for the submission of views, proposals, and remarks, and that no application is made to the Pharmacological Evaluation Unit and Registration Unit regarding the “parenteral products containing Ascorbic acid (vitamin C) alone” during the referred process.

Spec. Pharm. Oğuzhan KOYUNCU on behalf of the President of the Agency Head of Department

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