ASCOR is indicated for the short term (up to 1 week) treatment of vitamin C deficiency in patients 1 year of age and older.

**INDICATIONS AND USAGE**

ASCOR is not indicated for prolonged administration (the recommended maximum duration of daily treatment for patients 2 years and older is approximately 1 week) or for treatment of vitamin C deficiency in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency. Patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency may be at increased risk for hemolysis during treatment with ascorbic acid because of the reaction of ascorbic acid with 6-phosphogluconate, a reaction that is present only in G6PD-deficient erythrocytes. Discontinue ASCOR if hemolysis is suspected and treat as needed.

**DOSE AND ADMINISTRATION**

**Supplied Dosage Forms:**

- Tablets: Tablets contain 100 mg of ascorbic acid (equivalent to 200 mg of ascorbic acid injection) for intravenous use.
- Injection: 25,000 mg /50 mL (500 mg/mL) supplied as a pharmaceutical Bulk Package (clear, colorless to pale yellow solution)

**Pharmacy Bulk Package**

- Each dose should be used as an undiluted intravenous infusion.
- To prepare the admixture for infusion, calculate the number of doses to provide the required volume of diluted ASCOR solution.
- The final solution must be isotonic.
- Add appropriate solutes, as necessary, to make the final solution isotonic.
- Each dose is intended for use in a single patient.
- Since one dose is a single unit dose (one time use), use only one time and discard the remainder of the vial.

**Dosage**

**Pediatric Patients age 1 year to less than 12 years**

- Administer 200 mg once daily
- Administer 100 mg once daily

**Adults and Pediatric Patients age 12 years and older**

- Administer 200 mg once daily
- Adjust dose to the individual patient’s needs

**Patients who are pregnant or lactating and patients with renal disease including renal impairment**

- Reduce dose is recommended (5.2).

- Hemolysis: Patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency may be at increased risk for hemolysis during treatment with ascorbic acid because of the reaction of ascorbic acid with 6-phosphogluconate, a reaction that is present only in G6PD-deficient erythrocytes. Discontinue ASCOR if hemolysis is suspected and treat as needed.

**Contraindications**

ASCOR is not indicated for treatment of vitamin C deficiency that is not associated with signs and symptoms of vitamin C deficiency. ASCOR is not indicated for treatment of vitamin C deficiency in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency. Patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency may be at increased risk for hemolysis during treatment with ascorbic acid because of the reaction of ascorbic acid with 6-phosphogluconate, a reaction that is present only in G6PD-deficient erythrocytes. Discontinue ASCOR if hemolysis is suspected and treat as needed.

**DOSAGE AND ADMINISTRATION**

**Supplied Dosage Forms:**

- Tablets: Tablets contain 100 mg of ascorbic acid (equivalent to 200 mg of ascorbic acid injection) for intravenous use.
- Injection: 25,000 mg /50 mL (500 mg/mL) supplied as a pharmaceutical Bulk Package (clear, colorless to pale yellow solution)

**Pharmacy Bulk Package**

- Each dose should be used as an undiluted intravenous infusion.
- To prepare the admixture for infusion, calculate the number of doses to provide the required volume of diluted ASCOR solution.
- The final solution must be isotonic.
- Add appropriate solutes, as necessary, to make the final solution isotonic.
- Each dose is intended for use in a single patient.
- Since one dose is a single unit dose (one time use), use only one time and discard the remainder of the vial.

**Dosage**

**Pediatric Patients age 1 year to less than 12 years**

- Administer 200 mg once daily
- Administer 100 mg once daily

**Adults and Pediatric Patients age 12 years and older**

- Administer 200 mg once daily
- Adjust dose to the individual patient’s needs

**Patients who are pregnant or lactating and patients with renal disease including renal impairment**

- Reduce dose is recommended (5.2).

- Hemolysis: Patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency may be at increased risk for hemolysis during treatment with ascorbic acid because of the reaction of ascorbic acid with 6-phosphogluconate, a reaction that is present only in G6PD-deficient erythrocytes. Discontinue ASCOR if hemolysis is suspected and treat as needed.
7.1 Antibiotics
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.2 Antihypertensives
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.3 Antineoplastics
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.4 Antipsychotics
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.5 Antiseptics
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.6 CNS Depressants
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.7 Diuretics
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.8 Nitrates
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.9 Nonsteroidal Anti-Inflammatory Drugs
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.10 Opiates
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.11 Penicillins
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.12 Phenothiazines
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.13 Quinolones
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.14 Sulfonamides
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.15 Theophylline
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.16 Thrombolytics
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

7.17 Tranquilizers
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

8.1 Acute Exposure
Ascorbic acid may cause nausea, vomiting, diarrhea, dizziness, headache, and lethargy.

8.2 Chronic Exposure
Ascorbic acid may cause nausea, vomiting, diarrhea, dizziness, headache, and lethargy.

8.3 Hemolysis
Ascorbic acid may cause hemolysis in patients with glucose-6-phosphate dehydrogenase deficiency.

8.4 Pediatric Use
Ascorbic acid is not indicated for use in pediatric patients less than 5 months of age.

8.5 Geriatric Use
Glimetamide filtration rate is decreased in elderly patients to a greater extent than in younger patients. Use ascorbic acid administration in elderly population is appropriate.

8.6 Renal Impairment
Ascorbic acid administration may increase creatinine clearance in adult patients with renal impairment.

8.7 Pregnancy
Ascorbic acid administration to pregnant women may increase the risk of hemolysis in patients with glucose-6-phosphate dehydrogenase deficiency.

8.8 Lactation
Ascorbic acid is excreted in human milk and crosses the placental barrier.

8.9 Drugs
Ascorbic acid may decrease activities of erythromycin, lincomycin, kanamycin, streptomycin, doxycycline, and lincomycin.

8.10 OVERDOSE
Overdose with ascorbic acid may cause nausea, vomiting, diarrhea, dizziness, headache, and lethargy.

8.11 DISPOSITION
Administered as a single intravenous dose in a diluent solution prepared for intravenous use.

9. CLINICAL PHARMACOLOGY
9.1 Mechanism of Action
9.2 Pharmacokinetics
9.3 Pharmacodynamics
9.4 Clinical Considerations
9.5 Nonclinica...