ASCOR is vitamin C indicated for the short term (up to 1 week) treatment of scurvy in adult and pediatric patients, age 5 months to less than 12 years. ASCOR is vitamin C indicated for oral administration to prevent scurvy in adult and pediatric patients, age 5 months to less than 12 years, in situations in which oral administration is not possible, insufficient or contraindicated.

ASCOR is not indicated for the treatment of vitamin C deficiency that is not associated with symptoms and signs of scurvy.

DOSE AND ADMINISTRATION

When given by intravenous infusion, prepare only one dose of ASCOR for use in one patient. Do not withdraw contents of a Pharmacy Bulk Package vial more than 4 hours before the intended time of administration. See Table 1: Recommended Dose of ASCOR and Infusion Rate of Diluted ASCOR Solution for doses needed for parenteral administration.

Dose

Recommended Dose

<table>
<thead>
<tr>
<th>Dosage (mg)</th>
<th>Infusion Rate (mg/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>15.0</td>
</tr>
<tr>
<td>200</td>
<td>30.0</td>
</tr>
<tr>
<td>333</td>
<td>50.0</td>
</tr>
<tr>
<td>500</td>
<td>83.3</td>
</tr>
</tbody>
</table>

In addition to the recommended doses in Table 1, reconstitute 500 mg of ASCOR with Sterile Water for Injection, 0.9% sodium chloride solution, or bacteriostatic water for injection to prepare a 5 mg/mL solution. See Table 2: Dose and Infusion Rate for Additional Doses for infusion rates based on the volume of diluent used.

Pregnant women, lactating women, and patients with glucose-6-phosphate dehydrogenase deficiency should not exceed the RDA. Patients with renal disease may be at increased risk receiving ASCOR. Discontinue ASCOR in patients with renal disease and those aged 2 years or less who may be at increased risk (5.1).

Contraindications

CONTRAINDICATIONS

Abbreviations: GI = gastrointestinal NS = not significant

Drug Interactions

WARNINGS AND PRECAUTIONS

1. Overdose

OVERDOSE

The maximum intravenous infusion dose of ASCOR is approximately 5,900 mOsmol/L). Prior to preparing the admixture for infusion, calculate the approximate osmolarity of the intended admixture for infusion. Add necessary solute to prepare the final solution isotonic. ASCOR is highly hypotonic; adjust solute content, as necessary, to make the final infusion solution isotonic.

3. Laboratory Test Procedures

Acidification: Ascorbic acid may cause acidification of the urine and result in decreased amphetamine serum levels and increased levels of amphetamine in the urine.

6. Contraindications

Other patients with glucose-6-phosphate dehydrogenase deficiency should not exceed the RDA. Patients with renal disease may be at increased risk receiving ASCOR. Discontinue ASCOR in patients with renal disease and those aged 2 years or less who may be at increased risk (5.1).

17. Patient Counseling Information

Patient Counseling Information

ASCOR is vitamin C indicated for intravenous use for the treatment of scurvy in adult and pediatric patients age 5 months and older, for whom oral administration is not possible, insufficient or contraindicated.

ASCOR is vitamin C indicated for oral administration to prevent scurvy in adult and pediatric patients, age 5 months to less than 12 years, in situations in which oral administration is not possible, insufficient or contraindicated.

ASCOR is vitamin C indicated for the short term (up to 1 week) treatment of scurvy in adult and pediatric patients, age 5 months to less than 12 years. ASCOR is vitamin C indicated for oral administration to prevent scurvy in adult and pediatric patients, age 5 months to less than 12 years, in situations in which oral administration is not possible, insufficient or contraindicated.

ASCOR is vitamin C indicated for intravenous use for the treatment of scurvy in adult and pediatric patients age 5 months and older, for whom oral administration is not possible, insufficient or contraindicated.
6. ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of this labeling:

- Oral contraceptive use
- Ocular hypotension and Neovascularization (See Warnings and Precautions (5.1))
- Hemolysis in patients with glaucoma

7. DRUG INTERACTIONS

Ascorbic acid decreases the activity of some enzymes, including amylase. This effect is seen with other vitamin C preparations as well. There is little evidence to support the use of ascorbic acid with the anticoagulation effects of warfarin, however, further studies are warranted.

7.1 Antihypertensives

Ascorbic acid may lead to inaccurate results (false negatives) on colorimetric reactions are generally those tests affected. Because the ascorbic acid (vitamin C) content in breast milk is at an adequate concentration, the developmental outcomes are seen in breast milk and crosses the placental barrier.

8.1 Pregnancy

There are no available data on use of ASCOR in pregnant women. It is not known whether ascorbic acid is excreted in the breast milk.

8.2 Lactation

Oral ascorbic acid in pregnant women is a drug-associated risk of adverse events during breastfeeding. Ascorbic acid (vitamin C) is an essential nutrient that is recommended during pregnancy. There is no evidence that it affects the breastfed child's health.

8.3 Children

There are no available data on the use of ASCOR in children. Rare adverse reactions have been reported in children older for whom oral administration is not possible. Ascorbic acid is indicated for the short term (up to 1 week) for the treatment of scurvy as described above.

8.4 Geriatric Use

Ascorbic acid may decrease the activity of some enzymes, including amylase. This effect is seen with other vitamin C preparations as well. There is little evidence to support the use of ascorbic acid with the anticoagulation effects of warfarin, however, further studies are warranted.

8.5 Renal Impairment

Ascorbic acid is not removed by hemodialysis. It has been reported that concurrent administration of ascorbic acid (vitamin C) with the anticoagulation effects of warfarin, however, further studies are warranted.

8.7 Drug/Nutrient Interactions

Ascorbic acid may lead to inaccurate results (false negatives) on colorimetric reactions are generally those tests affected. Because the ascorbic acid (vitamin C) content in breast milk is at an adequate concentration, the developmental outcomes are seen in breast milk and crosses the placental barrier.

8.8 Other Interactions

Ascorbic acid is not removed by hemodialysis. It has been reported that concurrent administration of ascorbic acid (vitamin C) with the anticoagulation effects of warfarin, however, further studies are warranted.

8.8.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

There are no available data on the use of ASCOR in children. Rare adverse reactions have been reported in children older for whom oral administration is not possible. Ascorbic acid is indicated for the short term (up to 1 week) for the treatment of scurvy as described above.

9. CLINICAL STUDIES

There are no available data on the use of ASCOR in children. Rare adverse reactions have been reported in children older for whom oral administration is not possible. Ascorbic acid is indicated for the short term (up to 1 week) for the treatment of scurvy as described above.

9.1 Pharmacokinetics

Ascorbic acid is not removed by hemodialysis. It has been reported that concurrent administration of ascorbic acid (vitamin C) with the anticoagulation effects of warfarin, however, further studies are warranted.

9.2 Pharmacodynamics

Ascorbic acid is not removed by hemodialysis. It has been reported that concurrent administration of ascorbic acid (vitamin C) with the anticoagulation effects of warfarin, however, further studies are warranted.

9.3 Pharmacology

Ascorbic acid is not removed by hemodialysis. It has been reported that concurrent administration of ascorbic acid (vitamin C) with the anticoagulation effects of warfarin, however, further studies are warranted.

10. OVERDOSAGE

Ascorbic acid is not removed by hemodialysis. It has been reported that concurrent administration of ascorbic acid (vitamin C) with the anticoagulation effects of warfarin, however, further studies are warranted.

11. DESCRIPTION

Each ASCOR, 50 mL, Pharmacy Bulk Package vial contains ascorbic acid (vitamin C), equivalent to 25,125 mg (50 mg/mL) of sodium ascorbate. Each tray pack contains 100,000 mg of sodium ascorbate.

12. CLINICAL PHARMACOLOGY

Ascorbic acid is not removed by hemodialysis. It has been reported that concurrent administration of ascorbic acid (vitamin C) with the anticoagulation effects of warfarin, however, further studies are warranted.

12.1 Mechanism of Action

Ascorbic acid is not removed by hemodialysis. It has been reported that concurrent administration of ascorbic acid (vitamin C) with the anticoagulation effects of warfarin, however, further studies are warranted.

12.3 Developmental and Functional Capacity

Ascorbic acid is not removed by hemodialysis. It has been reported that concurrent administration of ascorbic acid (vitamin C) with the anticoagulation effects of warfarin, however, further studies are warranted.

12.4 Special Populations

Ascorbic acid is not removed by hemodialysis. It has been reported that concurrent administration of ascorbic acid (vitamin C) with the anticoagulation effects of warfarin, however, further studies are warranted.

12.5 Monitoring Laboratory Tests

Ascorbic acid is not removed by hemodialysis. It has been reported that concurrent administration of ascorbic acid (vitamin C) with the anticoagulation effects of warfarin, however, further studies are warranted.

13. PATIENT COUNSELING INFORMATION

Ascorbic acid is not removed by hemodialysis. It has been reported that concurrent administration of ascorbic acid (vitamin C) with the anticoagulation effects of warfarin, however, further studies are warranted.

15. MANUFACTURER

Ascorbic acid is not removed by hemodialysis. It has been reported that concurrent administration of ascorbic acid (vitamin C) with the anticoagulation effects of warfarin, however, further studies are warranted.

Ascorbic acid is not removed by hemodialysis. It has been reported that concurrent administration of ascorbic acid (vitamin C) with the anticoagulation effects of warfarin, however, further studies are warranted.