

Ascor[®] (ascorbic acid) – New drug approval

- On October 3, 2017, [McGuff Pharmaceuticals announced](#) the FDA approval of [Ascor \(ascorbic acid\) injection](#), for short term (up to 1 week) 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 not indicated for the treatment of vitamin C deficiency that is not associated with signs and symptoms of scurvy.
- In a single pharmacokinetic study, 8 adult subjects were given a single intravenous (IV) dose of 1,000 mg ascorbic acid (5 times the largest recommended single dose) infused over a 30-minute period. The mean peak exposure to ascorbic acid was 436.2 µM and occurred at the end of the 30 minute infusion.
- Warnings and precautions of Ascor include oxalate nephropathy and nephrolithiasis, hemolysis in patients with glucose-6-phosphate dehydrogenase deficiency, and laboratory test interference.
- The most common adverse reactions with Ascor use were pain and swelling at the site of infusion.
- Ascor is supplied as a pharmacy bulk package (PBP), which is intended for dispensing of single doses to multiple patients in a pharmacy admixture program and is restricted to the preparation of admixtures for infusion. The recommended dose for IV infusion should be prepared based on the patient population.

Patient Population	Ascor Once Daily Dose
Patient ages 5 months to < 12 months	50 mg
Patient ages 1 year to < 11 years	100 mg
Adults and pediatric patients ≥ 11 years old	200 mg

- Ascor must be diluted prior to use and all the dispensing from the PBP completed within 4 hours. Each dose must be used immediately.
 - The maximum recommended duration of treatment with Ascor is 7 days. If no improvement in scorbutic symptoms is observed after one week of treatment, the patient may be retreated until resolution of scorbutic symptoms is observed.
 - Repeat dosing is not recommended in pediatric patients < 11 years of age.
- McGuff's launch plans for Ascor are pending. Ascor will be supplied as a pharmacy bulk package containing 25,000 mg/50 mL (500 mg/mL).