Subject: Important Drug Administration Information for Specific Lots of Ascor® (Ascorbic Acid Injection, USP)
NDC 67157-101-50 and NDC 67157-101-51

November 13, 2025

Dear Healthcare Provider,

McGuff Pharmaceuticals Inc. would like to inform you of important safety information regarding **Ascor® Ascorbic Acid Injection USP.**

Potential Safety Issue

A routine facility recertification identified a condition that theoretically may impact sterility assurance for specific lots of Ascor® Ascorbic Acid Injection. While all affected lots passed sterility, endotoxin, and particulate testing, and no contamination complaints or adverse events have been reported, an independent Health Hazard Evaluation concluded that the probability of adverse health consequences is remote.

Out of an abundance of caution, and to ensure patient safety and patient access, each vial of these lots will be accompanied by a 0.2 µm filtered IV extension set for use during administration of Ascor® Ascorbic Acid Injection USP.

Impacted lots:

25D0081, 25D0091, 25D0111, 25D0121, 25E0021, 25E0031, 25E0041, 25E0051, 25F0011, 25F0021, 25F0031, 25F0051, 25F0061, 25F0091, 25F0101, 25G0011, 25G0021, 25G0031, 25G0041

Recommendations for Healthcare Providers

- Administer Ascor® Ascorbic Acid Injection USP using the accompanied 0.2 µm filtered IV extension set only in healthcare settings where patients can be appropriately monitored.
- Monitor patients during and after administration for signs and symptoms of infection or pyrogenic reaction, such as fever, chills, rigors, tachycardia, malaise, or hypotension not otherwise explained by the patient's clinical condition.
- Discontinue use immediately if contamination or sterility failure is suspected and provide supportive medical management as clinically indicated.

<u>Reporting Adverse Events and Medication Errors</u>

Heath care providers and patients are encouraged to report adverse events and medication errors in patients who have been given Ascor® Ascorbic Acid Injection USP to McGuff Medical at 1-800-603-4795.

McGUFF
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2921 W. MacArthur Blvd.
Suite 141
Santa Ana, Ca 92704-6929

TOLL FREE: 800.603.4795
TEL: 714.545.2495
FAX: 877.444.1155
EMAIL:
pharmaceuticalanswers@mcguff.com
WEBSITE:
mcguffpharmaceuticals.com

Adverse events, medication errors or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- **Regular mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

You may also contact our medical information department at 1-800-603-4795 if you have any questions about the information contained in this letter or the safe and effective use of Ascor® Ascorbic Acid Injection USP. This letter is not intended to be a complete description of the benefits and risks related to the use of Ascor® Ascorbic Acid Injection USP. Please refer to the enclosed full prescribing information.

For additional information, please call 1-800-603-4795

Sincerely,

Regulatory Affairs Management
McGuff Pharmaceuticals, inc.

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