COMPANY ANNOUNCEMENT

ICU Medical Issues a Voluntary Nationwide Recall of Aminosyn II 15%, An Amino Acid Injection, Sulfite Free IV Solution Due to the Presence of Particulate Matter

Summary

Company Announcement Date:

September 03, 2021

FDA Publish Date:

September 07, 2021

Product Type:

Drugs

Reason for Announcement:

Presence of visible particulate matter

Company Name:

ICU Medical, Inc.

Brand Name:

Hospira

Product Description:

Aminosyn II, 15%, An Amino Acid Injection, Sulfite

Company Announcement

ICU Medical, Inc. is voluntarily recalling one lot (2,112 units) of Aminosyn II, 15%, An Amino Acid Injection, Sulfite Free intravenous (IV) solution to the hospital/user level due to the presence of visible particulate matter identified as fibers, hair, and proteinaceous material along with other particles. ICU Medical became aware of this issue while inspecting retain samples as part of routine process.

Administration of a drug product that contains particulate matter could result in adverse events ranging from inflammation at the site of injection to more serious events that could include the formation of a blood clot obstructing the flow of blood which could lead to end-organ damage or death. To date, ICU Medical, Inc. has not received reports of adverse events or illness related to this recall.

Aminosyn II, Sulfite-Free, (an amino acid injection) infused with dextrose by peripheral vein infusion is indicated as a source of nitrogen in the nutritional support of patients with adequate stores of body fat, in whom, for short periods of time, oral nutrition cannot be tolerated, is undesirable, or inadequate. Aminosyn II can be administered peripherally with dilute (5 to 10%) dextrose solution and I.V. fat emulsion as a source of nutritional support. This form of nutritional support can help to preserve protein and reduce the breakdown of organic or inorganic materials, such as proteins, sugars, fatty acids, etc. in stress conditions where oral intake is inadequate. Aminosyn II is also indicated for central vein infusion to prevent or reverse excreting more nitrogen than is being taken in in patients where the intestinal tract, by the oral, surgical opening into the stomach for the introduction of food or surgical procedure for a feeding tube routes cannot or should not be used and gastrointestinal absorption of protein is impaired. Product was distributed nationwide both by ICU Medical direct to customers and through medical distributors. The product is for human use only.

ICU Medical acquired this product from Hospira, a Pfizer company; therefore, the affected product contains a Hospira NDC number and a Hospira label. The affected product lot, manufactured in the U.S. by ICU Medical in November 2020, is listed below:

NDC Number / Catalog Number	Product Description	Lot Number	Expiration Date	Configuration	Manufacture Date	Distribution Dates
NDC: 0409-7171-17 Catalog Number: 07171-17	Aminosyn® II 15% An Amino Acid Injection, Sulfite-Free	4989094	01-Apr-2022	Pharmacy Bulk Package 2-liter Flexible Container	November 2020	January 2021 – March 2021

ICU Medical is notifying its distributors and customers of this recall by letter and is arranging for the return of all recalled products.

Hospitals/distributors that have product that is being recalled should stop use/further distribution and return to place of purchase.

Customers with questions regarding this recall can call ICU Medical at 1-844-654-7780 Monday through Friday between the hours of 8 a.m. and 5 p.m. Central time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these drug products.

Adverse reactions or quality problems experienced with the use of this product may 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 (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: Download form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) 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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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About ICU Medical, Inc.

ICU Medical, Inc. (Nasdaq: ICUI) is one of the world's leading pure-play infusion therapy companies with global operations and a wide-ranging product portfolio that includes IV solutions, IV smart pumps, dedicated and non-dedicated IV sets and needlefree connectors, along with pain management and safety software technology designed to help meet clinical, safety and workflow goals. In addition, the company manufactures automated pharmacy IV compounding systems with workflow technology, closed systems transfer devices for hazardous IV drugs, and cardiac monitoring systems to optimize patient fluid levels. ICU Medical is headquartered in San Clemente, California. On February 3, 2017, ICU Medical completed the acquisition of the Hospira Infusion Systems business from Pfizer. More information about ICU Medical, Inc. can be found at www.icumed.com (//www.icumed.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

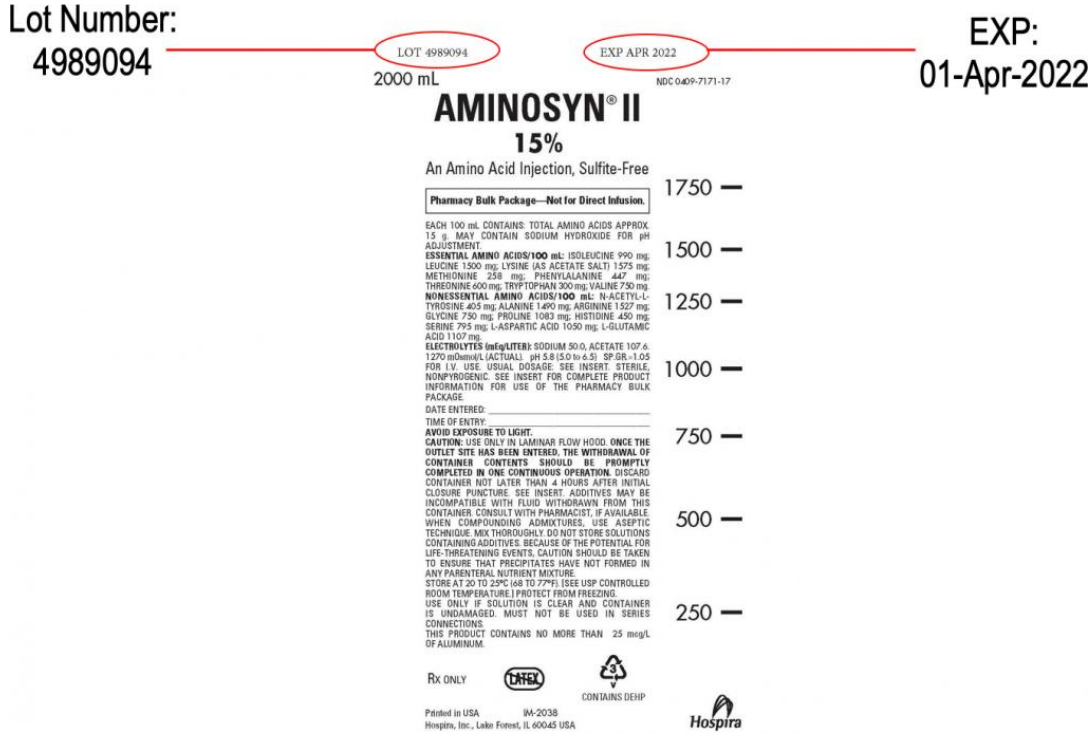
Company Contact Information

Consumers:

ICU Medical

1-844-654-7780

Product Photos


Lot Number:
4989094
LOT 4989094
EXP APR 2022
EXP:
01-Apr-2022
2000 mL
NDC 0409-7171-17
AMINOSYN® II
15%
An Amino Acid Injection, Sulfite-Free
Pharmacy Bulk Package—Not for Direct Infusion.
EACH 100 mL CONTAINS: TOTAL AMINO ACIDS APPROX. 15 g. MAY CONTAIN SODIUM HYDROXIDE FOR pH ADJUSTMENT.
ESSENTIAL AMINO ACIDS/100 mL: ISOLEUCINE 990 mg; LEUCINE 1500 mg; LYSINE (AS ACETATE SALT) 1575 mg; METHIONINE 258 mg; PHENYLALANINE 447 mg; THREONINE 600 mg; TRYPTOPHAN 300 mg; VALINE 750 mg.
NONESSENTIAL AMINO ACIDS/100 mL: N-ACETYL-L-TYROSINE 405 mg; ALANINE 1,490 mg; ARGININE 1,527 mg; GLYCINE 750 mg; PROLINE 1083 mg; HISTIDINE 450 mg; SERINE 795 mg; L-ASPARTIC ACID 1050 mg; L-GLUTAMIC ACID 1107 mg.
ELECTROLYTES (mEq/LITER): SODIUM 50.0, ACETATE 107.6.
1270 mOsmol/L (ACTUAL). pH 5.8 (5.0 to 6.5). SP.GR.=1.05
FOR I.V. USE. USUAL DOSAGE: SEE INSERT. STERILE, NONPYROGENIC. SEE INSERT FOR COMPLETE PRODUCT INFORMATION FOR USE OF THE PHARMACY BULK PACKAGE.
DATE ENTERED:
TIME OF ENTRY:
AVOID EXPOSURE TO LIGHT.
CAUTION: USE ONLY IN LAMINAR FLOW HOOD. ONCE THE OUTLET SITE HAS BEEN ENTERED, THE WITHDRAWAL OF CONTAINER CONTENTS SHOULD BE PROMPTLY COMPLETED IN ONE CONTINUOUS OPERATION. DISCARD CONTAINER NOT LATER THAN 4 HOURS AFTER INITIAL CLOSURE PUNCTURE. SEE INSERT. ADDITIVES MAY BE INCOMPATIBLE WITH FLUID WITHDRAWN FROM THIS CONTAINER. CONSULT WITH PHARMACIST, IF AVAILABLE. WHEN COMPOUNDING ADMIXTURES, USE ASEPTIC TECHNIQUE. MIX THOROUGHLY. DO NOT STORE SOLUTIONS CONTAINING ADDITIVES. BECAUSE OF THE POTENTIAL FOR LIFE-THREATENING EVENTS, CAUTION SHOULD BE TAKEN TO ENSURE THAT PRECIPITATES HAVE NOT FORMED IN ANY PARENTERAL NUTRIENT MIXTURE.
STORE AT 20 TO 25°C (68 TO 77°F). [SEE USP CONTROLLED ROOM TEMPERATURE.] PROTECT FROM FREEZING.
USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.
THIS PRODUCT CONTAINS NO MORE THAN 25 mcg/L OF ALUMINUM.
Rx ONLY
LATEX
CONTAINS DEHP
Printed in USA IM-2038
Hospira, Inc., Lake Forest, IL 60045 USA
Hospira
1750
1500
1250
1000
750
500
250

More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls-market-withdrawals-safety-alerts)