Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Lupin Pharmaceuticals, Inc. Issues Voluntary Recall of Ceftriaxone for Injection USP, 250mg, 500mg, 1g and 2g

For Immediate Release

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Contact

Consumers

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Announcement

Lupin Pharmaceuticals, Inc. is voluntarily recalling 5 lots of Ceftriaxone for Injection, USP, 250mg, 10 lots of Ceftriaxone for Injection, USP, 500mg, 24 lots of Ceftriaxone for Injection, USP, 1g and 3 lots of Ceftriaxone for Injection, USP 2g, to the hospital/physician level. The products have been found to contain visual grey particulate matter in reconstituted vials.

Improper piercing and use of a needle greater than 21 gauge (larger internal diameter), while reconstituting the vial, can push rubber flecks into the solution. There were no grey flecks seen prior to the reconstitution of the vials and the issue was identified upon standard visual inspection prior to patient administration.

If injected, this product (containing rubber particulate matter from the stopper) could cause vein irritation/phlebitis or pulmonary embolic events that could result in permanent impairment of body function or damage to body structures, such as the lungs and vascular system. In addition, as ceftriaxone can be administered intramuscularly, the use of the product may result in local muscle inflammation and/or abscesses.

Ceftriaxone for Injection, USP, is used as a sterile, semi-synthetic, broad-spectrum cephalosporin antibiotic for intravenous or intramuscular administration. It is used to reduce the development of drug-resistant bacteria and maintain the effectiveness of ceftriaxone sodium and other antibacterial drugs Ceftriaxone for Injection, USP, should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria. To date, the Company has not received any reports of adverse events related to the recalled lots.

Ceftriaxone for Injection, USP, is packaged in a glass vial, in pack of 10, containing 10 vials in a carton, with NDC 68180-611-10, 68180-622-10, 68180-633-10, 68180-644-10 and as single pack containing one glass vial in a carton with NDC 68180-611-01, 68180-622-01, 68180-633-01.

The lots of Ceftriaxone for Injection USP, 250mg, 500mg, 1g and 2g included in the recall are listed in the table below:

Product Name	NDC	Lot Number	Expiration Date
Ceftriaxone for Injection USP, 250mg	68180-611-10	C600182	09/2019
	68180-611-10	C600136	08/2019
	68180-611-01	C600142	08/2019
	68180-611-10	C700147	05/2020
	68180-611-10	C700207	09/2020
Ceftriaxone for Injection USP, 500mg	68180-622-01	C600218	09/2019
	68180-622-10	C600219	09/2019
	68180-622-10	C600126	08/2019
	68180-622-10	C600127	08/2019
	68180-622-10	C600137	08/2019
	68180-622-10	C600143	08/2019
	68180-622-01	C600173	08/2019
	68180-622-10	C700146	05/2020
	68180-622-10	C700208	09/2020
	68180-622-10	C700209	09/2020
Ceftriaxone for Injection USP, 1g	68180-633-10	C600106	05/2019
	68180-633-10	C600108	05/2019
	68180-633-01	C600110	05/2019
	68180-633-10	C600174	09/2019
	68180-633-10	C600179	09/2019
	68180-633-10	C600180	09/2019
	68180-633-10	C600181	09/2019
	68180-633-10	C700110	03/2020

	68180-633-10	C700111	03/2020
	68180-633-10	C700131	05/2020
	68180-633-10	C700132	05/2020
	68180-633-10	C700138	05/2020
	68180-633-01	C700143	05/2020
	68180-633-10	C600128	08/2019
	68180-633-01	C600130	08/2019
	68180-633-10	C600138	08/2019
	68180-633-10	C700108	03/2020
	68180-633-10	C700109	03/2020
	68180-633-10	C700112	03/2020
	68180-633-10	C700129	05/2020
	68180-633-10	C700130	05/2020
	68180-633-10	C700142	05/2020
	68180-633-10	C700145	05/2020
	68180-633-01	C700113	03/2020
Ceftriaxone for Injection USP, 2g	68180-644-10	C600109	05/2019
	68180-644-10	C600129	08/2019
	68180-644-10	C600135	08/2019

Ceftriaxone for Injection, USP, 250mg, Ceftriaxone for Injection, USP, 500mg, Ceftriaxone for Injection, USP, 1g and Ceftriaxone for Injection, USP, 2g were distributed Nationwide to Wholesalers / Drug chains.

Lupin Pharmaceuticals Inc. is notifying its distributors by phone and through recall notification and is arranging for return of all recalled product lots.

Hospitals / Physicians that have Ceftriaxone for Injection, USP, which are being recalled should stop using and return to Genco Pharmaceuticals Services “a subsidiary of FedEx Supply Chain” 6101 North 64th Street, Milwaukee, WI 53218, Tel: (855) 838-5786.

Questions regarding this recall can be made by contacting GENCO Pharmaceutical Services at 1-855-838-5786 Monday – Friday 7:30 am to 6:00 pm EST. For reimbursement, please have the recalled lots returned to GENCO, the lot number can be found on the side of the vial. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

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:**www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm)**

- Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (http://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

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

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