Lupin Pharmaceuticals, Inc.

January 7, 2019

MANUFACTURED BY:
Lupin Limited
Mandideep 462 046 INDIA

MANUFACTURED FOR:
Lupin Pharmaceuticals, Inc.
111 South Calvert Street
Baltimore, Maryland 21202
United States

Dear Healthcare Partner,

URGENT: DRUG RECALL – HOSPITAL/PHYSICIAN LEVEL

Ceftriaxone for Injection USP, 250mg
Ceftriaxone for Injection USP, 500mg
Ceftriaxone for Injection USP, 1g
Ceftriaxone for Injection USP, 2g

Lupin Pharmaceuticals, Inc. is voluntarily recalling lot **C600182 Expiry September 2019, C600136, C600142 Expiry August 2019, C700147 Expiry May 2020, C700207 Expiry September 2020 of Ceftriaxone for Injection USP 250mg, C600126, C600127, C600137, C600143, C600173 Expiry August 2019, C600218, C600219 Expiry September 2019, C700146 Expiry May 2020, C700208, C700209 Expiry September 2020 of Ceftriaxone for Injection USP 500mg, C600106, C600108, C600110 Expiry May 2019, C600128, C600130, C600138 Expiry August 2019, C600174, C600179, C600180, C600181 Expiry September 2019, C700108, C700109, C700112, C700110, C700111, C700113 Expiry March 2020, C700131, C700132, C700138, C700143, C700129, C700130, C700142, C700145 Expiry May 2020 of Ceftriaxone for Injection USP 1g** , and **C600109 Expiry May 2019, C600129, C600135 Expiry August 2019 of Ceftriaxone for Injection USP 2g** to the **Hospital/Physician** level. These product lots are being precautionarily recalled, due to repetitive product complaints indicating grey flecks in constituted vials.

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.

The recalled lots were distributed between August 23, 2016 and July 12, 2018 to wholesalers, drug chains and mail order pharmacies nationwide.

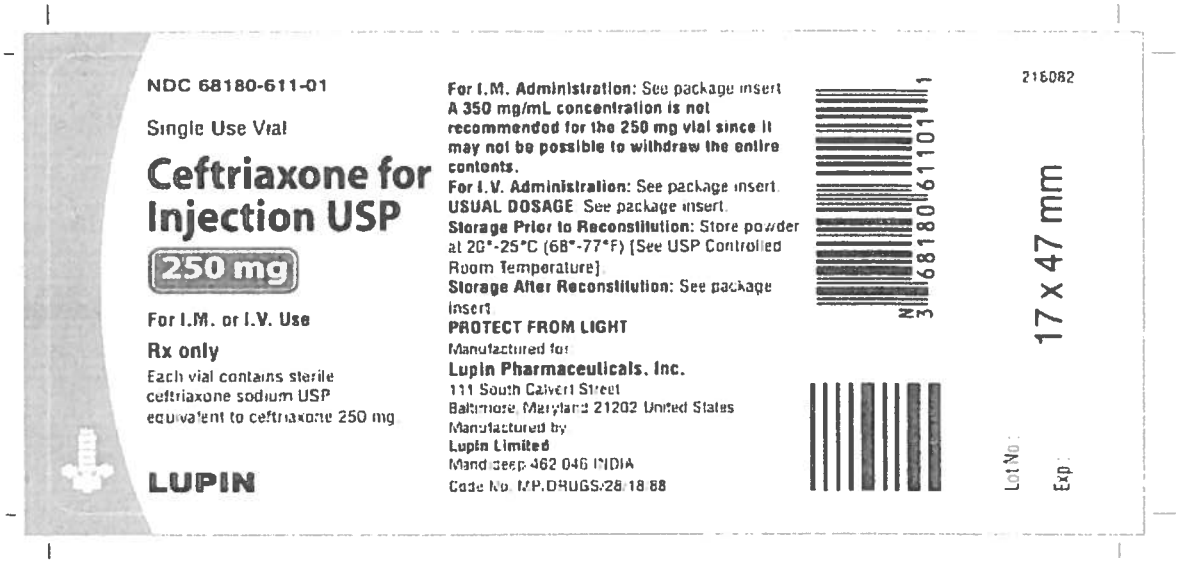
Lupin Pharmaceuticals, Inc.

Immediately examine your inventory and quarantine the product lots subject to recall. Wholesalers and distributors should forward this notification to the retailers, hospitals and physicians. Wholesalers and distributors who have the affected product lots in their inventory should contact GENCO Pharmaceutical Services at 1-855-838-5786 Monday – Friday 7:30 am to 6:00 pm EST. Retailers, hospitals, physicians and distributors are requested to return any product that they may have in their possession to the wholesaler that they purchased the product through. Lupin in turn, will issue credit to that wholesaler. For reimbursement, please have the recalled lots returned to GENCO on or before March 15, 2019. The lot number can be found on the side of the vial.

Ceftriaxone for Injection USP 250mg, 500mg, 1g and 2g are supplied as below:

Strength	Description
250mg	Ceftriaxone for Injection USP, 250mg is supplied as a White (white to yellowish orange) powder filled in a glass vial. NDC 68180-611-01 (1 in 1 Box) and 68180-611-10 (10 in 1 Box)
500mg	Ceftriaxone for Injection USP, 500mg is supplied as a White (white to yellowish orange) powder filled in a glass vial. NDC 68180-622-01 (1 in 1 Box) and 68180-622-10 (10 in 1 Box)
1g	Ceftriaxone for Injection USP, 1g is supplied as a White (white to yellowish orange) powder filled in a glass vial. NDC 68180-633-01 (1 in 1 Box) and 68180-633-10 (10 in 1 Box)
2g	Ceftriaxone for Injection USP, 2g is supplied as a White (white to yellowish orange) powder filled in a glass vial. NDC 68180-644-10 (10 in 1 Box)

Product label:



Lupin Pharmaceuticals, Inc.

NDC 68180-622-01

Single Use Vial

Ceftriaxone for Injection USP

500 mg

For I.M. or I.V. Use

Rx only

Each vial contains sterile ceftriaxone sodium USP equivalent to ceftriaxone 500 mg

LUPIN

For I.M. Administration: Reconstitute with 1 mL 1% Lidocaine Hydrochloride Injection (USP) or Sterile Water for Injection (USP). Each 1 mL of solution contains approximately 350 mg equivalent of ceftriaxone
For I.V. Administration: See package insert
USUAL DOSAGE: See package insert
Storage Prior to Reconstitution: Store powder at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]
Storage After Reconstitution: See package insert
PROTECT FROM LIGHT

Manufactured for:
Lupin Pharmaceuticals, Inc.
111 South Calvert Street
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Lupin Limited
Mandideep 462 046 INDIA
Code No. MP/DRUGS/28.18.88

N 3 68180 62201 7

218083

17 x 47 mm

Lot No

Exp.

NDC 68180-633-01

Single Use Vial

Ceftriaxone for Injection USP

1 g

For I.M. or I.V. Use

Rx only

Each vial contains sterile ceftriaxone sodium USP equivalent to ceftriaxone 1 g

LUPIN

For I.M. Administration: Reconstitute with 2.1 mL 1% Lidocaine Hydrochloride Injection (USP) or Sterile Water for Injection (USP). Each 1 mL of solution contains approximately 350 mg equivalent of ceftriaxone
For I.V. Administration: See package insert
USUAL DOSAGE: See package insert
Storage Prior to Reconstitution: Store powder at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]
Storage After Reconstitution: See package insert
PROTECT FROM LIGHT

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N 3 68180 63301 3

218084

17 x 47 mm

Lot No

Exp.

NDC 68180-644-01

Single Use Vial

Ceftriaxone for Injection USP

2 g

For I.M. or I.V. Use

Rx only

Each vial contains sterile ceftriaxone sodium USP equivalent to ceftriaxone 2 g

LUPIN

For I.M. Administration: Reconstitute with 4.2 mL 1% Lidocaine Hydrochloride Injection (USP) or Sterile Water for Injection (USP). Each 1 mL of solution contains approximately 350 mg equivalent of ceftriaxone
For I.V. Administration: See package insert.
USUAL DOSAGE: See package insert.
Storage Prior to Reconstitution: Store powder at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]
Storage After Reconstitution: See package insert
PROTECT FROM LIGHT

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Mandideep 462 046 INDIA
Code No. MP/DRUGS/28.18.88

N 3 68180 64401 9

218085

17 x 47 mm

Lot No

Exp.

HARBORPLACE TOWER. 111 SOUTH CALVERT STREET. 21ST FLOOR. BALTIMORE. MD 21202. TEL: 410-576-2000 FAX: 410-576-2221
www.lupinpharmaceuticals.com

Lupin Pharmaceuticals, Inc.

This recall should be carried out to the **Hospital/Physician** level.

A COMPLETE PACKAGE OF INFORMATION INCLUDING A REPLY CARD AND A PREPAID FEDEX AUTHORIZED RETURN SERVICE℠ SHIPPING LABEL WILL BE MAILED WITHIN (5) BUSINESS DAYS. THE REPLY CARDS AND RECALLED PRODUCT SHOULD BE SHIPPED TO:

Attention:

GENCO Pharmaceutical Services "a subsidiary of FedEx supply chain"
6101 North 64th Street
Milwaukee, WI 53218
Tel: 1-855-838-5786

We appreciate your immediate attention to this matter. This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

Anurag Mishra
Sr.Manager, Quality
Lupin Pharmaceuticals, Inc.