Lupin – Recall of Ceftriaxone

- On January 17, 2019, Lupin announced a voluntary, patient-level recall of several lots of ceftriaxone injection due to product complaints indicating grey flecks in constituted vials. The grey flecks have been identified as rubber particulate matter from the stopper.

- The recalled lots were distributed nationwide between August 23, 2016 and July 12, 2018:

Product Description	NDC#	Lot# (Expiration Date)
Ceftriaxone 250 mg injection	68180-611-01; 68180-611-10	C600136 (8/2019); C600142 (8/2019); C600182 (9/2019); C700147 (5/2020); C700207 (9/2020)
Ceftriaxone 500 mg injection	68180-622-01; 68180-622-10	C700209 (9/2020); C600127 (8/2019); C600137 (8/2019); C600143 (8/2019); C600173 (8/2019); C600218 (9/2019); C600219 (9/2019); C700146 (5/2020); C700208 (9/2020); C600126 (8/2019)
Ceftriaxone 1 g injection	68180-633-01; 68180-633-10	C600181 (9/2019); C600106 (5/2019); C700131 (5/2020); C700130 (5/2020); C700129 (5/2020); C700113 (3/2020); C700112 (3/2020); C700111 (3/2020); C700110 (3/2020); C700138 (5/2020); C700108 (3/2020); C700142 (5/2020); C600180 (9/2019); C600179 (9/2019); C600174 (9/2019); C600138 (8/2019); C600130 (8/2019); C600128 (8/2019); C600110 (5/2019); C600108 (5/2019); C700109 (3/2020); C700143 (5/2020); C700145 (5/2020); C700132 (5/2020)
Ceftriaxone 2 g injection	68180-644-01; 68180-644-10	C600129 (8/2019); C600135 (8/2019); C600109 (5/2019)

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- Ceftriaxone is indicated to treat the following infections when caused by susceptible organisms: lower respiratory tract infections, acute bacterial otitis media, skin and skin structure infections, urinary tract infections, uncomplicated gonorrhea, pelvic inflammatory disease, bacterial septicemia, bone and joint infections, intra-abdominal infections, meningitis, and surgical prophylaxis.

- Per Lupin, if product containing particulate matter is injected this could cause 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.

- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled ceftriaxone.

- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately. Patients should return the product back to retailers. Hospitals, physicians, retailers and distributors are requested to return any product that they may have in their possession to the wholesaler that they purchased the product through.

- For more information regarding this recall, contact Genco (appointed company for Lupin) at **1-855-838-5786**.