BioSpectrum the business of Bio & Health Sciences

Lupin Pharma issues voluntary recall of Ceftriaxone for Injection

07 January 2019 | News

Ceftriaxone for Injection, USP, is used as a sterile, semi-synthetic, broad-spectrum cephalosporin antibiotic for intravenous or intramuscular administration

Lupin Pharmaceuticals 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.

Ceftriaxone for Injection, USP, is packaged in a glass vial, in pack of 10, containing 10 vials in a carton, with NDC