Generic Name:
Levoleucovorin injection
Trade Name:
No trade name
Company:
Mylan Institutional
Notes:

Mylan Institutional is conducting a voluntary nationwide recall of two lots of levoleucovorin injection (# 67457-601-30 and #67457-601-30), 250 mg/25 mL, to the consumer/user level. The lots, manufactured by Alidac Pharmaceuticals and distributed by Mylan, contain particulate matter identified as copper salts. The particulate matter was discovered during 12-month stability testing.

I.V. administration of a solution containing particulates could lead to local irritation, vasculitis/phlebitis, antigenic or allergic reactions, and microvascular obstruction, including pulmonary embolism.

Levoleucovorin injection is indicated for rescue after high-dose methotrexate therapy in osteosarcoma; for diminishing the toxicity and counteracting the effects of impaired methotrexate elimination and of inadvertent overdose of folic acid antagonists; and for use in combination chemotherapy with 5-fluorouracil in the palliative treatment of patients with advanced metastatic colorectal cancer.

Levoleucovorin injection 250 mg contains 25-mL sterile solution in a single-use vial. Each vial is packaged in a carton containing one single-use vial. The batches were distributed in the United States between August 2017 and July 2018.

To date, Mylan has not received any reports of adverse events related to this recall.

Medication Monitor Categories:
Alerts and Recalls