Generic Name:
Ketorolac tromethamine injection USP 60 mg/2 mL
Trade Name:
No trade name
Company:
Sagent Pharmaceuticals/Zydus (Cadila Healthcare Limited)
Notes:

Sagent Pharmaceuticals announced a voluntary nationwide recall of one lot (#M813513) of ketorolac tromethamine injection USP 60 mg/2 mL (30 mg per mL) because microbial growth was detected during a routine simulation of the manufacturing process. This product was manufactured by Zydus (Cadila Healthcare Limited) and distributed by Sagent.

Adult patients administered the product intravenously are at most risk of a serious bloodstream infection of sepsis. The possibility of a breach in sterility assurance in distributed product, while remote, cannot be eliminated. No batches of distributed product have been identified as actually containing microorganisms. To date, Sagent has not received reports of any adverse events associated with this issue.

The product is a NSAID indicated for the short-term (up to 5 days in adults) management of moderately severe acute pain that requires analgesia at the opioid level. It is supplied in 2-ml glass tubular vials. The lot number being recalled was distributed to hospitals, wholesalers, and distributors nationwide from January to March 2019.

Medication Monitor Categories:
Alerts and Recalls