Sagent Pharmaceuticals – Recall of ketorolac tromethamine injection

- On May 1, 2019, the FDA announced a voluntary user-level recall of one lot of Sagent Pharmaceuticals' ketorolac tromethamine injection due to microbial growth detected during a routine simulation of the manufacturing process, which represents the potential introduction of microorganisms into the products.

- The recalled product was distributed nationwide from January - March 2019:

Product Description	NDC#	Lot# (Expiration Date)
Ketorolac tromethamine injection, 60 mg per 2 mL (30 mg per 1 mL)	25021-701-02	M813513 (2/2020)

- Ketorolac tromethamine injection, is a nonsteroidal anti-inflammatory drug (NSAID), indicated for the short-term (≤ 5 days), management of moderately severe acute pain that requires analgesia at the opioid level, usually in a postoperative setting.

- Per 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 the recalled product.

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

- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.

- For more information regarding this recall, contact Sagent Pharmaceuticals at **1-866-625-1618**.