Sagent Pharmaceuticals, Inc.

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Sagent Pharmaceuticals Issues Voluntary Nationwide Recall of Ketorolac Tromethamine Injection, USP, 60mg/2mL (30mg per mL) Due to Lack of Sterility Assurance

CUSTOMER SUPPORT:
Customer Call Center
(866) 625-1618

MEDICAL AFFAIRS
(866) 625-1618, Option 3

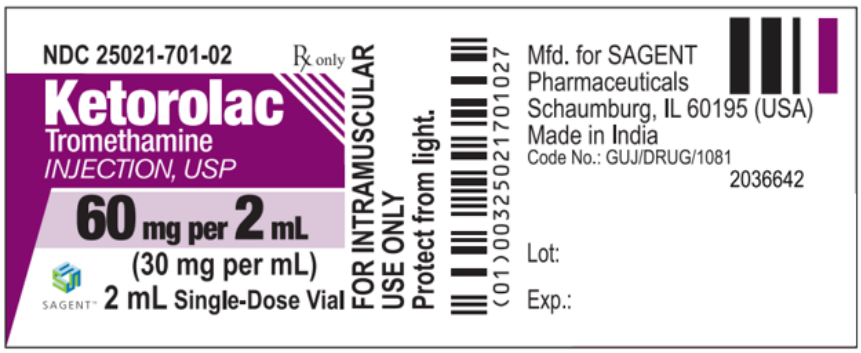
FOR IMMEDIATE RELEASE - SCHAUMBURG, IL – 4/30/2019 – Sagent Pharmaceuticals, Inc. today announced the voluntary nationwide recall of one lot of Ketorolac Tromethamine Injection, USP, 60mg/2mL (30mg per mL). This product was manufactured by Zydus (Cadila Healthcare Limited) and distributed by Sagent Pharmaceuticals, Inc. Sagent has initiated this voluntary recall of Ketorolac Tromethamine Injection, USP to the to the user level due to microbial growth detected during a routine simulation of the manufacturing process, which represents the potential introduction of microorganisms into the products.

Adult patients administered the product intravenously are at most risk of a serious bloodstream infection of sepsis (serious condition resulting from the presence of harmful microorganisms in the blood and the body's response to their presence, potentially leading to shock and death). 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.

Ketorolac Tromethamine Injection, USP, is a nonsteroidal anti-inflammatory drug (NSAID), is indicated for the short-term (up to 5 days in adults), management of moderately severe acute pain that requires analgesia at the opioid level.

The product is supplied in 2 ml glass tubular vials. The lot number being recalled was distributed to hospitals, wholesalers and distributors nationwide from January – March 2019.

Product	Lot Number	Expiration Date	NDC Number	Distribution Dates
Ketorolac Tromethamine Injection, USP, 60mg per 2mL (30mg per 1mL)	M813513	Feb-2020	25021-701-02	January – March 2019



Customers are being notified by fax, email, FedEx, and/or certified mail that includes arrangements for return of all recalled product. Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return the recalled lot of product. Customers who may have further distributed this product have been requested to identify their customers and notify them at once of this product recall. Consumers/distributors/retailers that have product which is being recalled should stop using product and return the recalled product. The necessary form by which to document this information as well as other information regarding this recall is available at www.Sagentpharma.com.

Customers or consumers with any questions about returning unused product should be directed to the customer call center at (866) 625-1618 M-F, 8am-7pm CST. Healthcare workers who have medical questions about Ketorolac Tromethamine Injection, USP, may contact Medical Affairs (866-625-1618, Option 3) M-F, 8am-5pm CST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.