May 6, 2019

COM-2019-019

Recall of Ketorolac Tromethamine Injection, USP, 60mg/2mL (30mg per mL) due to Lack of Sterility Assurance

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on April 30, 2019 the US Food and Drug Administration (FDA) issued a statement that Sagent Pharmaceuticals Inc. is recalling one lot of ketorolac tromethamine injection 60mg/2mL (30mg/mL). This is due to microbial growth detected during a routine simulation of the manufacturing process, which represents the potential introduction of microorganisms into the products. The possibility of a breach in sterility assurance in distributed product, while remote, cannot be eliminated. The lot being recalled was distributed to hospitals, wholesalers and distributors nationwide from January to March 2019. The affected product of the recall is detailed on Table 1.

Table 1. Affected product of Ketorolac

NDC	Product	Affected Lot	Expiration Date
25021-701-02	Ketorolac Tromethamine Injection USP 60mg/2mL (30mg/mL)	M813513	GS014045

The Pharmacy must:

1. Identify if they have the product in inventory and immediately stop using and dispensing the product. The necessary form by which to document this information as well as other information regarding this recall is available at www.sagentpharma.com.
2. Contact all members that in the previous 90 days received the recalled medication and advised them to talk to their doctor. Patients should not discontinue taking the medication without a doctor's permission.
3. Patients or customers wishing to return product may contact Sagent Pharmaceuticals Inc. customer call center at 1-866-625-1618, Monday – Friday, 8 am - 7 pm

For additional information visit:
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sagent-pharmaceuticals-issues-voluntary-nationwide-recall-ketorolac-tromethamine-injection-usp

Department of Clinical Pharmacy

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com