March 2020 **COM-2020-013**

RECALL NOTIFICATION

DATE:
March 4, 2020

DRUG NAME:
Ketorolac Tromethamine Injection, USP 30mg/mL, 1 mL Vial

COMPANY:
Hikma Pharmaceuticals USA Inc.

REASON:
Potential Presence of Small Particulates

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. The clinical team wants to communicate you with the latest up-to-date information on the Food and Drug Administration (FDA) drug recalls.

Affected product:

NDC	Product description	Lot #	Expiration date
00641-6042-25	**Ketorolac Tromethamine Injection 30mg/mL - Size [1mL Fill/2mL Vial]**	038366	Mar-2020
		048365	Apr-2020
		048367	Apr-2020
		078301	Jul-2020
		078303	Jul-2020
		118358	Nov-2020
		019413	Jan-2021
		029353	Feb-2021

Pharmacy required action:

- Identify if they have the product in inventory and immediately stop using and dispensing it.
- Contact all members that in the previous 90 days received the recalled medication and advise them to return the drug and contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using the recalled drug product.

Contact information:

- Recall related inquires: Hikma Pharmaceuticals USA Inc. (P): (800) 631-2174, (E): usrecall@hikma.com,(Fax): (732) 542-0940, Hours of operation, M-F: 8:00am-7pm (EST)
- Product Returns: Qualanex LLC, Qualanex LLC, 1410 Harris Road, Libertyville, IL 60048-2435, (E): recall@qualanex.com

Note:
Remember that any adverse event related to this or any other pharmaceutical product can be reported to the FDA's MedWatch Adverse Event Reporting program:

- 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

Additional information // Reference:

- Center for Drug Evaluation and Research. (2020, March 5). Hikma Pharmaceuticals USA Inc. Extends Voluntary Nationwide Recall of Ketorolac Tromethamine Injection, USP 30mg/mL, 1mL Fill/2mL Vials Due to the Potential Presence of Small Particulates. Retrieved from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/hikma-pharmaceuticals-usa-inc-extends-voluntary-nationwide-recall-ketorolac-tromethamine-injection?utm_campaign=FDA MedWatch: Ketorolac Tromethamine Injection by Hikma Pharmaceuticals USA&utm_medium=email&utm_source=Eloqua

Best regards,

PharmPix Clinical Department

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