RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Ketorolac tromethamine injection Recall Alert

Date of Notice: 03/04/2020

Brief Description of Recall

On March 4, 2020, Hikma Pharmaceuticals USA, Inc. extended its previously announced recall of ketorolac tromethamine injection due to the presence of small visible particulate matters of a gelatinous/oily nature.

Administration of the affected drug could potentially result in the deposition of particulates in the lungs of patients, which could result in multiple pulmonary microemboli with subsequent acute respiratory distress for patients receiving the drug intravenously.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Ketorolac Tromethamine Injection 30mg/mL	0641-6042-25	038366	03/2020
		048365 048367	04/2020
		078301 078303	07/2020
		118358	11/2020
		019413	01/2021
		029353	02/2021

Prescriber Information

Hikma has not received any reports of adverse events related to this issue.

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
- Regular Mail or Fax: Download form 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

Member Information

Members should contact their doctor if they have experienced any problems that may be related to taking or using this drug product.

For recall inquiries, please contact Hikma using the information provided below:

Contact	Contact Information	Support
Hikma Pharmaceuticals USA Inc. – Customer Service	(P): (800) 631-2174 (E): usrecall@hikma.com (F): (732) 542-0940 Hours of operation, M-F: 8:00am-7pm (EST)	Recall related inquires
Qualanex LLC (Hikma 3rd Party Recall Service Provider)	Qualanex LLC 1410 Harris Road Libertyville, IL 60048-2435 (E): recall@qualanex.com	Product Returns

RxAdvance Response

RxAdvance is in the process of contacting members and prescribers to advise them of this recall.