AMPHASTAR PHARMACEUTICALS, INC.
11570 6th Street, Rancho Cucamonga, CA 91730 · Telephone: (909) 980-9484 · Fax: (909) 980-8296

August 24th, 2017

URGENT: DRUG RECALL NOTICE UPDATE

RE: Ketorolac Tromethamine Injection, USP, 30mg/mL, 1mL vial
NDC 0548-9021-00, Various Lots

Dear Customer:

Initial notification was provided on August 17th, 2017 of Amphastar Pharmaceuticals, Inc. recall of its Ketorolac Tromethamine Injection, USP product due to the presence of visible particulate in vials identified as ketorolac calcium salt. The purpose of this follow-up notification is to provide additional information with regard to this recall, which was not previously provided for or explicitly stated in the previous communication. Note that this update does NOT include additional lots from those previously specified in the initial notification and is solely to provide the additional information requested by the U.S. Food and Drug Administration outlined below:

a) **Health Hazard Evaluation:** Use of affected product could result in possible health hazard. Intramuscular (IM) or intravenous (IV) administration of the product theoretically could result in localized inflammation, allergic reaction, granuloma formation or microembolic effects (IV only). Delay of therapy may occur due to particulates blocking the infusion of solution or due to observation of particulates at the point of care. To date, there has been no information from the field reporting any adverse events from the affected lots of medication, or any other commercial lots of Ketorolac Tromethamine Injection, USP. The potential hazard of ketorolac calcium particulates should be of low clinical significance based on Amphastar's current analysis of this issue.

b) Our Customer Service Department can be reached at 1-800-423-4136, Monday through Friday from the hours of 7am to 5pm PST to handle questions and/or concerns related to the recall, including providing return authorizations. Information with regard to the recall can also be found at www.amphastar.com.

c) In addition to the depiction provided at the top of this notice, examples of the sample labels (carton label, vial label) have been provided on the Amphastar website (www.amphastar.com) under the red "Drug Recall Notice" link for visual reference of the Ketorolac Tromethamine Injection, USP product.

This recall continues to be made with the knowledge and cooperation of the Food and Drug Administration. We appreciate your timely assistance in this matter.

Sincerely,

Diane Gerst
Exec. Vice President, Quality Assurance/Regulatory Affairs

Enclosure: (1) Ketorolac Tromethamine Injection Lots Being Recalled by Amphastar (as previously provided)

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NDC Number	LOT Number	EXP Date
0548-9021-00	XI002A6	12/2017
0548-9021-00	XI003A6	12/2017
0548-9021-00	XI004G6	06/2018
0548-9021-00	XI005G6	06/2018
0548-9021-00	XI007H6	07/2018
0548-9021-00	XI008I6	08/2018
0548-9021-00	XI009I6	08/2018
0548-9021-00	XI010I6	08/2018
0548-9021-00	XI011I6	08/2018
0548-9021-00	XI012J6	09/2018
0548-9021-00	XI013J6	09/2018
0548-9021-00	XI015K6	10/2018
0548-9021-00	XI016L6	11/2018
0548-9021-00	XI018A7	12/2018
0548-9021-00	XI019A7	12/2018
0548-9021-00	XI020B7	01/2019
0548-9021-00	XI021B7	01/2019
0548-9021-00	XI022C7	02/2019
0548-9021-00	XI023C7	02/2019
0548-9021-00	XI025D7	03/2019

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August 17, 2017

URGENT: DRUG RECALL NOTICE

RE: Ketorolac Tromethamine Injection, USP, 30 mg/mL, 1 mL vial
NDC 0548-9021-00, Various Lots

Dear Customer:

Our records show that your facility has purchased Ketorolac Tromethamine Injection, USP during the period commencing 04/28/2016 to 04/25/2017.

Amphastar Pharmaceuticals, Inc. is recalling the above mentioned products with the lot numbers listed on the attached sheet due to presence of visible particulate in vials that has been identified as crystalline ketorolac calcium salt.

Use of this product could result in possible health hazard.

Anyone with an existing inventory of the recalled lots should stop use and distribution, and quarantine the product immediately. This recall is being carried out to the medical facility/retail level. Customers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the medical facility/retail level.

Please return the enclosed card immediately, providing the requested information, and contact our Customer Service Department at 1-800-423-4136 for return authorization. After receiving authorization, you may return product to our Rancho Cucamonga, California plant, Attention: Quality Assurance Manager. You will be reimbursed by a credit memo for the returned goods.

This recall is being made with the knowledge of the Food and Drug Administration.

We appreciate your timely assistance in this matter.

Sincerely,

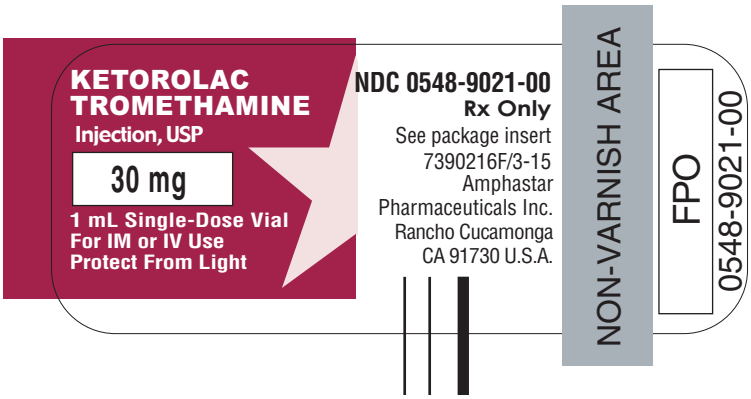
Diane Gerst
Exec Vice President, Quality Assurance/Regulatory Affairs

Enclosure: Ketorolac Tromethamine Injection Lots Being Recalled by Amphastar

List of Ketorolac Tromethamine Injection Lots Being Recalled by Amphastar

NDC Number	LOT Number	EXP Date
0548-9021-00	XI002A6	12/2017
0548-9021-00	XI003A6	12/2017
0548-9021-00	XI004G6	06/2018
0548-9021-00	XI005G6	06/2018
0548-9021-00	XI007H6	07/2018
0548-9021-00	XI008I6	08/2018
0548-9021-00	XI009I6	08/2018
0548-9021-00	XI010I6	08/2018
0548-9021-00	XI011I6	08/2018
0548-9021-00	XI012J6	09/2018
0548-9021-00	XI013J6	09/2018
0548-9021-00	XI015K6	10/2018
0548-9021-00	XI016L6	11/2018
0548-9021-00	XI018A7	12/2018
0548-9021-00	XI019A7	12/2018
0548-9021-00	XI020B7	01/2019
0548-9021-00	XI021B7	01/2019
0548-9021-00	XI022C7	02/2019
0548-9021-00	XI023C7	02/2019
0548-9021-00	XI025D7	03/2019

Sample Ketorolac Vial Label



Sample Ketorolac Carton