COMMUNICATION

COM-2023-058

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OCTOBER
2023

URGENT
PLEASE
REVIEW

Recall Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

10/03/2023

Drug Information:

National Drug Code

75788-115-04

Product Description:

BETAXOLOL TABLETS, USP 10MG

Batch Number

17853A

Expiration Date

JUNE 2027

Company:

KVK-TECH, INC.

QUESTIONS

Call KVK-TECH, INC. at (215) 579-1842 Ext: 6002 Monday – Friday, 8:00 am – 6:00 pm ET or by email at customerservice@kvktech.com.

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Betaxolol Tablets

It is for this reason that we are notifying you that on 10.03.2023 the US Food and Drug Administration published a drug recall for the following product(s): Betaxolol Tablets, USP 10 mg.

Pharmacy Required Action:

Identify if the product is in inventory and immediately stop using and dispensing it. The product should be returned to the place of purchase or as directed in the recall notification.

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Reason for Recall:

KVK-Tech, Inc. is voluntarily recalling one lot of Betaxolol Tablets, USP 10 mg to the consumer level. The batch is being recalled as a precautionary measure due to a single Oxycodone HCl tablet 5 mg foreign tablet found on the packaging line during the line clearance after the subject batch was packaged.

The betaxolol package insert warns about slowing in the heart rate in elderly patients which is likely to be exacerbated by inadvertent opioid administration. Some patients prescribed low-dose betaxolol might have compromised heart and lung function that is also likely to be exacerbated by an opioid. Moreover, there are minor differences in appearance between betaxolol 10mg tablets and oxycodone 5mg tablets, not likely noticed by a regular user of the 10mg betaxolol tablet.

Reason for Recall (cont.):

Inadvertent exposure to a controlled substance, such as oxycodone, in infants, children, and the elderly are likely to result in significant slowing in breathing, known as respiratory depression, which is a serious health risk.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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 can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Recall Communication Number COM-2023-058 October 2023

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REFERENCES:

1. U.S. Food and Drug Administration. (2023). KVK-Tech, Inc. KVK-Tech, Inc. Issues Voluntary Nationwide Recall of One Lot of Betaxolol Tablets, USP 10 mg (Batch Number: 17853A) as a Precautionary Measure Due to a Single Foreign Tablet Found During the Line Clearance After the Batch was Packaged. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/kvk-tech-inc-issues-voluntary-nationwide-recall-one-lot-betaxolol-tablets-usp-10-mg-batch-number
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program-https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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