COMMUNICATION

COM-2023-010

07
MARCH
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:

03/02/2023

Drug Information:

National Drug Code

Refer to table included in the notification.

Product Description

BRIMONIDINE TARTRATE OPHTHALMIC SOLUTION 0.15%

Lot Number

Refer to table included in the notification.

Expiration Date

Refer to table included in the notification.

Company:

APOTEX CORP.

QUESTIONS

Call Apotex Corp. at 1.800.706.5575, Monday – Friday from 9:00 a.m. to 5:00 p.m. ET, or email UScustomerservice@Apotex.com.

Call Inmar Rx Solutions at 1.855.272.1273 Monday – Friday from 9:00 a.m. to 5:00 p.m. ET.

Brimonidine Tartrate Ophthalmic Solution

It is for this reason that we are notifying you that on 03/02/2023 the US Food and Drug Administration published a drug recall for the following product(s): Brimonidine tartrate ophthalmic solution, 0.15%.

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:

Apotex Corp. is voluntarily recalling at the consumer level six lots of brimonidine tartrate ophthalmic solution 0.15% due to cracks that have developed in some of the unit's caps of the solution bottles. There is a possibility that broken cap may impact sterility and if so, the possibility of adverse events.

The six lots can be identified by NDC numbers stated on the carton and label of the product. The lot number and expiry date are located on the top flap of the carton and to the left side of the product description on the bottle label beside the barcode. These lots were distributed nationwide in the USA between April 5, 2022, to February 22, 2023.

Apotex Corp. is notifying all impacted direct accounts of this voluntary recall via email and mail and is arranging for return of all recalled products.

Product	Strength	Pack Size	NDC	Lot Number	Expiry Date
Brimonidine Tartrate Ophthalmic Solution	0.15%	5mL	60505-0564-1	TJ9848	02/2024
				TJ9849	
				TK0258	04/2024
				TK5341	
		10mL	60505-0564-2	TK0261	
		15mL	60505-0564-3	TK0262	

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-2023-010 March 2023

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REFERENCES:

1. U.S. Food and Drug Administration. (2023). Apotex Corp. Issues Voluntary Nationwide Recall of Brimonidine Tartrate Ophthalmic Solution, 0.15% Due to Cracks that Have Developed in Some of the Units Caps of the Bottles. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-brimonidine-tartrate-ophthalmic-solution-015-due
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