COMMUNICATION

COM-2022-071

27
DECEMBER
2022

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:

12/21/2022

Drug Information:

National Drug Code

68180-0558-09 (20MG TABLETS)

68180-0554-09 (40MG TABLETS)

Product Description

QUINAPRIL TABLETS USP, 20MG AND 40MG

Lot Number

20MG TABLETS: G102929

40MG TABLETS: G100533, G100534, G203071

Expiration Date

20MG TABLETS: 04/2023

40MG TABLETS: 12/2022 (LOT # G100533, G100534), 03/2024 (LOT # G203071)

Company:

Lupin Pharmaceuticals Inc.

QUESTIONS

Call Inmar Rx Solutions, Inc. at 877.538.8445 Monday – Friday from 9:00 a.m. to 5:00 p.m. ET.

Quinapril Tablets.

It is for this reason that we are notifying you that on 12/21/2022 the US Food and Drug Administration published a drug recall for the following product(s): Quinapril tablets USP, 20mg and 40mg.

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:

Lupin Pharmaceuticals Inc. is voluntarily recalling four (4) lots of quinapril tablets to the consumer level due to the presence of a nitrosamine impurity, N-Nitroso-Quinapril, observed in recent testing above the Acceptable Daily Intake (ADI) level. To date, Lupin has received no reports of illness that appear to relate to this issue.

Nitrosamines are common in water and foods. Everyone is exposed to some level of nitrosamines. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time.

Lupin Pharmaceuticals Inc. is notifying its wholesalers, distributors, drug chains, mail order pharmacies and supermarkets by phone and through recall notification and is arranging for the return of all the recalled product lots.

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/.

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Pharmacy Benefit Management
Expires 12/01/2025

REFERENCES:
1. U.S. Food and Drug Administration. (2022). Lupin Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Four Lots of Quinapril Tablets Due to Potential Presence of N-Nitroso-Quinapril Impurity. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/lupin-pharmaceuticals-inc-issues-voluntary-nationwide-recall-four-lots-quinapril-tablets-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

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