COMMUNICATION

COM-2023-057

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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:

09/28/2023

Drug Information:

National Drug Code

75788-115-04

Product Description:

BREXAFEMME™ (IBREXAFUNGERP TABLETS) 150MG

Lot Number

LF21000008

LF22000051

Expiration Date

LF21000008 – Exp. November 2023

LF22000051 – Exp. November 2025

Company:

SCYNEXIS, INC.

QUESTIONS

Call SEDGWICK at 1-877-551-7154. Office hours: Monday to Friday, 8:00 AM to 5:00 PM ET.

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Brexafemme™

It is for this reason that we are notifying you that on 09.28.2023 the US Food and Drug Administration published a drug recall for the following product(s): BREXAFEMME™ (ibrexafungerp) tablets 150mg.

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:

SCYNEXIS, Inc. is conducting a voluntary nationwide recall of 2 lots of BREXAFEMME™ (ibrexafungerp tablets) to the consumer level in the US market due to potential cross contamination with a non-antibacterial ß-lactam drug substance in the ibrexafungerp citrate used to manufacture the BREXAFEMME™ tablets.

The potential cross contamination with a non-antibacterial beta-lactam drug substance could lead to hypersensitivity reactions such as swelling, rash, urticaria and anaphylaxis, a potentially life-threatening adverse reaction.

To date, SCYNEXIS has not received any reports of adverse events established to be due to the possible beta-lactam cross contamination.

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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REFERENCES:

1. U.S. Food and Drug Administration. (2023). Scynexis, Inc., SCYNEXIS Issues a Voluntary Nationwide Recall of BREXAFEMME® (ibrexafungerp tablets) Due to Potential for Cross Contamination with a Non-Antibacterial ßlactam Drug Substance: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/scynexis-issues-voluntary-nationwide-recall-brexafemmer-ibrexafungerp-tablets-due-potential-cross
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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