COMMUNICATION

2021-046

21 September 2021

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 you with the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

09/13/2021

Drug Information:

National Drug Code

49938-110-01

Product Description

Ruzurgi™ (amifampridine) 10mg tablets

Control Numbers

18038, 18039, 18079

Expiration Date

March 2023 (control numbers: 18038, 18039), May 2023 (control number: 18079)

Company:

Jacobus Pharmaceuticals Company Inc.

QUESTIONS

Call JACOBUS PHARMACEUTICALS COMPANY INC. at 609-799-8221, ext. 2120

Monday – Friday from 9:00 a.m. to 5:00 p.m. EST.

Ruzurgi™

For this reason, we are notifying you that on 09/13/2021, the US Food and Drug Administration published a drug recall for the following product(s): Ruzurgi™ (amifampridine) 10mg tablets.

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 that may be related to taking or using this product must contact their physician.

Reason for Recall:

Jacobus Pharmaceuticals Company Inc. is voluntarily recalling 3 lots of Ruzurgi™ (amifampridine) 10mg tablets. The products have been found to be contaminated with yeast, mold, and aerobic bacteria based on laboratory test results.

Oral products heavily contaminated with yeast, mold, and aerobic bacteria may result in serious and life-threatening infections. The use of the defective product in patients with underlying immunosuppressive conditions such as Lambert Eaton Syndrome (LEMS) increases the concern for serious infections.

Consumers that have Ruzurgi™ (amifampridine) should return the product.

If shipping via US Postal Service ship to:	If shipping via courier service (i.e., UPS, FedEx, etc.) ship to:
Jacobus Pharmaceutical Company, Inc. P.O. Box 5290, Princeton, NJ 08540.	Jacobus Pharmaceutical Company, Inc. IRL Building 31 Schalks Crossing Road Plainsboro, NJ 08356.

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 046 September 2021

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Pharmacy Benefit Management
Expires 12/01/2022

REFERENCES:

1. Jacobus Pharmaceutical Company Inc. Issues Voluntary Worldwide Recall of Ruzurgi® (amifampridine) 10 mg Tablets Due to Yeast, Mold, and Bacterial Contamination. U.S. Food and Drug Administration. (2021). Retrieved from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/jacobus-pharmaceutical-company-inc-issues-voluntary-worldwide-recall-ruzurgir-amifampridine-10-mg.
2. MedWatch Online Voluntary Reporting Form. Accessdata.fda.gov. (2021). Retrieved from https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home.