COMMUNICATION

COM-2022-053

29
SEPTEMBER
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 you with the latest up-to-date drug recall information.

U.S. Food & Drug Administration Publication Date:

09/27/2022

Drug Information:

National Drug Code

55150-154-10

Product Description

ACYCLOVIR INTRAVENOUS PRODUCT

Batch Number

AC22006

Expiration Date

AUGUST 2023

Company:

EUGIA US LLC

CONTACT INFORMATION
RETURN OF RECALLED DRUG

Qualanex
1-888-280-2046 from 7:00AM to 4:00 PM, Monday – Friday CST
Email: recall@qualanex.com

QUESTIONS

Drug Safety Department
1-866-850-2876 from 8:00 AM to 5:00 PM, Monday – Friday EST
Email: pvg@aurobindousa.com

Acyclovir Sodium Injection 500 mg per 10 mL (50mg/mL)

It is for this reason that we are notifying you that on 09.27.2022 the US Food and Drug Administration published a drug recall for the following product: Acyclovir Sodium Injection 500mg per 10 mL (50mg/mL).

Pharmacy Required Action:

Identify if the product is in inventory, 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:

A product complaint was made regarding the presence of a dark red, brown, and black particulate inside the vial.

The administration of an intravenous product containing particulates has the potential to result in inflammation, allergic reactions, or circulatory system complications which could be life-threatening.

To date, Eugia US LLC has not received reports of any adverse events or identifiable safety concerns attributed to the product consumed for this lot.

Wholesale customers and health professionals that have the product lot which is being recalled should immediately place the recalled lot on hold and contact Qualanex.

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-2022-053 SEPTEMBER 2022

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ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

REFERENCES:

1. U.S. Food and Drug Administration. (2022). *Eugia US LLC Issues Voluntary Nationwide Recall of Acyclovir Sodium Injection 500 mg per 10 mL (50 mg/mL), Due to the Presence of Particulate Matter*. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/eugia-us-llc-issues-voluntary-nationwide-recall-acyclovir-sodium-injection-500-mg-10-ml-50-mgml-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

2 Street 1, Suite 500
Guaynabo, PR 00968

Tel. 787.522.5252
Fax 866.912.2830

www.pharmpix.com
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