COMMUNICATION

COM-2024-061

24 SEPTEMBER 2024

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:

09/23/2024

Drug Information:

National Drug Code

61958-2901-02

Product Description

Veklury® (remdesivir) for injection 100mg/vial

Lot Number

47035CFA

Expiration Date

November 2025

Company:

Gilead Sciences, Inc

QUESTIONS

Call Gilead Medical Information at 1-866-633-4474 Monday – Friday from 5:00 a.m. to 6:00 p.m. PST or through their website at www.askgileadmedical.com.

Veklury For Injection 100mg/vial

It is for this reason that we are notifying you that on 09.23.2024 the U.S. Food and Drug Administration published a drug recall for the following product(s): Veklury (remdesivir) for injection 100mg/vial.

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:

Gilead Sciences, Inc. is issuing a voluntary recall of one lot of Veklury (remdesivir) for Injection 100 mg/vial to the consumer level. Gilead received a customer complaint and confirmed the presence of a glass particle in the vial during the company's investigation. Veklury lot 47035CFA was distributed nationwide in the United States, from 07/16/2024 to 08/07/2024.

Risk Statement:

The administration of an injectable product that contains glass particles may result in local irritation or swelling in response to the foreign material. The glass particulate can potentially travel, through the blood vessels, to various organs and block blood vessels in the heart, lungs or brain which can cause stroke and even lead to death. To date, Gilead has not received any reports of adverse events related to this recall.

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- ext.219. 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-2024-061 September 2024

pharmpix
POWERED BY ONEARK

REFERENCES

1. U.S. Food and Drug Administration. (2024). Gilead issues voluntary nationwide recall of one lot of Veklury (Remdesivir) for injection 100 mg/vial due to the presence of a glass particle. Retrieved September 23, 2024, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/gilead-issues-voluntary-nationwide-recall-one-lot-veklury-remdesivir-injection-100-mgvial-due
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program- Available at: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

urac ACCREDITED Pharmacy Benefit Management Expires 12/01/2025

2 Street 1, Suite 500
Guaynabo, PR 00968

Tel. 787.522.5252
Fax 866.912.2830

www.pharmpix.com
FRM-CL-000126-001

CLINICAL PEARLS BY PHARMPIX