COMMUNICATION

COM-2023-071

27
NOVEMBER
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:

11/21/2023

Drug Information:

National Drug Code

50419-392-01

Product Description

VITRAKVI™ (LAROTRECTINIB) ORAL SOLUTION 20 MG/ML

Lot Number

2114228

Expiration Date

FEBRUARY 29, 2024

Company:

BAYER

QUESTIONS

Call BAYER MEDICAL INFORMATION CALL CENTER at 888.842.2937, Monday – Friday from 8:30 a.m. to 8:00 p.m. EST.

Call QUALANEX at 888.280.2043 Monday – Friday from 7:00 a.m. to 4:00 p.m. CST or e-mail to Recall@qualanex.com.

Vitrakvi™ Oral Solution

It is for this reason that we are notifying you that on 11.21.2023 the U.S. Food and Drug Administration published a drug recall for the following product(s): Vitrakvi™ (larotrectinib) oral solution 20 mg/mL in 100 mL glass bottles.

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:

Bayer is voluntarily recalling one lot of Vitrakvi™ (larotrectinib) oral solution, 20 mg/mL in 100mL glass bottles, to the consumer level, due to *Penicillium brevicompactum* contamination in the product.

There is a reasonable probability that microbial contamination of the oral solution can result in life threatening infections such as invasive fungal infections of the blood or pneumonia. Immunocompromised individuals are at most risk of these infections.

To date, Bayer has not received any reports of adverse events related to this recall.
This particular lot was distributed nationwide to wholesale distributors and specialty pharmacies between January 3, 2023, and February 13, 2023.

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-2023-071 November 2023

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REFERENCES:

1. U.S. Food and Drug Administration. (2023). Bayer Issues Voluntary Recall Nationwide of VITRAKVI® (larotrectinib) Oral Solution 20 mg/mL Due to Presence of Microbial Contamination.https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bayer-issues-voluntary-recall-nationwide-vitrakvir-larotrectinib-oral-solution-20-mgml-due-presence
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

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