Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC23-062-CG
November 22, 2023

FDA announced that, Bayer is voluntarily recalling one lot of Vitrakvi® (larotrectinib) Oral Solution 20 mg/mL in 100mL glass bottles to the consumer/user level. The product is being recalled due to microbial contamination identified as Penicillium brevicompactum observed during routine ongoing stability testing. The impacted lot of Vitrakvi® is packaged in a 100mL glass bottle with NDC# 50419-392-01 and is identified with Lot# 2114228 and an expiration date of February 29, 2024. Lot# 2114228 was distributed to wholesale distributors and specialty pharmacies nationwide between January 3, 2023, and February 13, 2023.

RECOMMENDATIONS

1. Bayer notified all distributors and pharmacies of this recall on November 8, 2023. Bayer has engaged Qualanex to manage the recall of the product down to the consumer level. Qualanex has notified Vitrakvi® distributors via a recall notification letter and will arrange for the return of the recalled lot from distributors, specialty pharmacies, and consumers. Consumers with general questions regarding this recall can contact Qualanex via e-mail at Recall@qualanex.com or toll free at **888-280-2043**, Monday-Friday between the hours of 7 a.m. and 4 p.m. Central Standard Time.

2. Consumers who have the recalled Vitrakvi® product should immediately stop use of this particular lot of product and contact their physician or healthcare provider if they have any questions, concerns or have experienced any problems related to Vitrakvi® Oral Solution 20 mg/mL

3. Patients or prescribers who have questions regarding the recall can contact **Bayer Medical Information Call Center** at **888-842-2937**, Monday-Friday between the hours of 8:30 a.m. and 8:00 p.m. Eastern Standard Time.

4. Review your inventory to identify existence of recalled products.

5. Expect patients to visit your pharmacy to deliver recalled products and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

FDA U.S. FOOD & DRUG ADMINISTRATION

Bayer Issues Voluntary Recall Nationwide of VITRAKVI® (larotrectinib) Oral Solution 20 mg/mL Due to Presence of Microbial Contamination

Summary:

Company Announcement Date:	November 17, 2023
FDA Publish Date:	November 21, 2023
Product Type:	Drugs
Reason for Announcement:	Microbial contamination identified as Penicillium brevicompactum
Company Name:	Bayer
Brand Name:	Bayer
Product Description:	Vitrakvi® (larotrectinib) Oral Solution 20 mg/mL in 100mL glass bottles

COMPANY ANNOUNCEMENT

FOR IMMEDIATE RELEASE - November 17, 2023 – WHIPPANY, N.J., Bayer is voluntarily recalling one lot of *Vitrakvi® (larotrectinib)* Oral Solution 20 mg/mL in 100mL glass bottles to the consumer/user level. The product is being recalled due to microbial contamination identified as *Penicillium brevicompactum* observed during routine ongoing stability testing.

Risk Statement: Given that *Vitrakvi®* is indicated for the treatment of solid tumors that are NTRK gene fusion positive, it is expected that patients on *Vitrakvi®* may be immunocompromised. Although there is little data in the literature on human pathology caused by *Penicillium brevicompactum*, there are cases of invasive disease caused by similar Penicillium species, particularly in patients with underlying immunosuppression. Therefore, there is a reasonable probability that ingestion of *Penicillium brevicompactum* in patients on *Vitrakvi®* with underlying immunosuppression may result in invasive fungal infections of the blood or pneumonia that can be life-threatening. To date, Bayer has not received any adverse events related to this recall.

The impacted lot of *Vitrakvi®* is packaged in a 100mL glass bottle with NDC# 50419-392-01 and is identified with Lot# 2114228 and an expiration date of February 29, 2024. Lot# 2114228 was distributed to wholesale distributors and specialty pharmacies nationwide between January 3, 2023, and February 13, 2023.

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Product bottle and carton label images and information on the lot number that falls under this recall is available below.

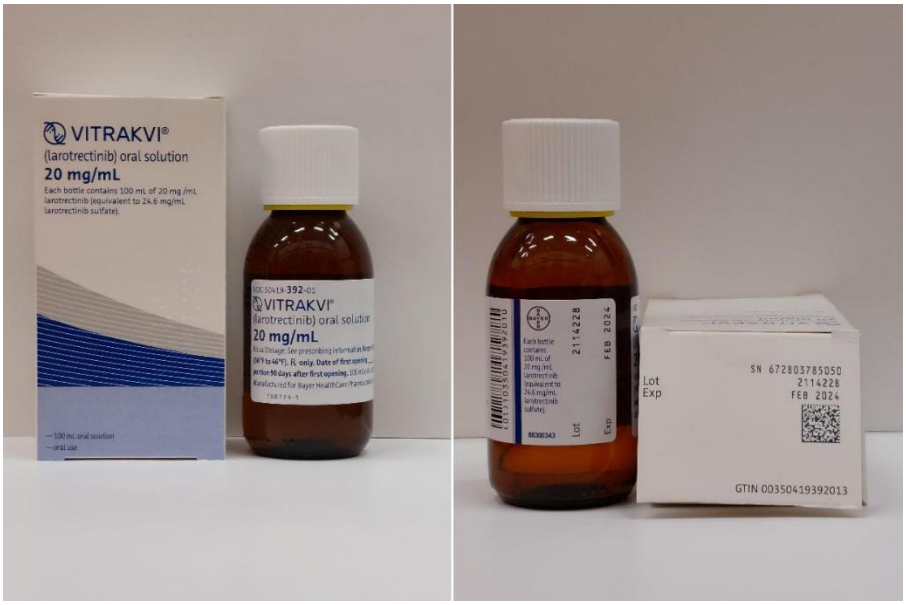
Bayer notified all distributors and pharmacies of this recall on November 8, 2023. Bayer has engaged Qualanex to manage the recall of the product down to the consumer level. Qualanex has notified *Vitrakvi®* distributors via a recall notification letter and will arrange for the return of the recalled lot from distributors, specialty pharmacies, and consumers. Consumers with general questions regarding this recall can contact Qualanex via e-mail at Recall@qualanex.com or toll free at 888-280-2043, Monday-Friday between the hours of 7 a.m. and 4 p.m. Central Standard Time.

Consumers who have the recalled *Vitrakvi®* product should immediately stop use of this particular lot of product and contact their physician or healthcare provider if they have any questions, concerns or have experienced any problems related to *Vitrakvi®* Oral Solution 20 mg/mL.

Patients or prescribers who have questions regarding the recall can contact Bayer Medical Information Call Center at 888-842-2937, Monday-Friday between the hours of 8:30 a.m. and 8:00 p.m. Eastern Standard Time.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form 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.



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