Nov. 21, 2023

Bayer issues voluntary recall nationwide of Vitrakvi (larotrectinib) oral solution 20 mg/mL due to presence of microbial contamination

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About this recall:

Bayer is voluntarily recalling one lot of Vitrakvi (larotrectinib) oral solution 20 mg/mL in 100 mL glass bottles to the consumer/user level. The recall is due to contamination that was found during testing of the product. Contamination was from the fungus Penicillium brevicompactum. **The recalled lot of Vitrakvi has an NDC of 50419-0392-01 and is identified as lot number 2114228 with an expiration date of Feb. 29, 2024**.

Vitrakvi is FDA-approved for the treatment of solid tumors that are NTRK gene fusion positive. Therefore, it is expected that patients receiving this medication may have a suppressed immune system.

What this means to you:

Cases of severe disease caused by similar fungus species to Penicillium brevicompactum have occurred, especially in patients whose immune systems are suppressed. Therefore, the potential exists that ingestion of Penicillium brevicompactum in patients with underlying immune system suppression could result in serious fungal infections of the blood or pneumonia that can be life-threatening.

Consumers who have the recalled Vitrakvi product should immediately stop use of this particular lot and contact their health care provider if they have any questions, concerns or have experienced any problems related to the recalled drug. Patients or prescribers who have questions regarding the recall can contact Bayer Medical Information Call Center at **888.842.2937**, Monday–Friday, 8:30 a.m.–8 p.m. Eastern Standard Time (EST). Alternatively, patients with general questions regarding this recall can contact Qualanex via email at **Recall@Qualanex.com** or toll-free at **888.280.2043**, Monday–Friday, 7 a.m.–4 p.m. Central Standard Time (CST).