Ukoniq™ (umbralisib) Tablets Withdrawal Alert

Date of Notice: June 1, 2022

Brief Description of Withdrawal Alert

Due to safety concerns, the U.S. Food and Drug Administration (FDA) has withdrawn its approval of Ukoniq™ (umbralisib). Ukoniq™ was approved to treat two specific types of lymphoma: marginal zone lymphoma (MZL) and follicular lymphoma (FL).

Updated findings from the UNITY-CLL clinical trial continued to show a possible increased risk of death in patients receiving Ukoniq™. As a result, the FDA determined the risks of treatment with Ukoniq™ outweigh its benefits. Based upon this determination, the drug's manufacturer, TG Therapeutics, announced it was voluntarily withdrawing Ukoniq™ from the market for the approved uses in MZL and FL.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
Ukoniq™ (umbralisib) tablets, 200 mg	73150-200-12	All lots	All dates

Prescriber Information

Healthcare professionals should stop prescribing Ukoniq™ and switch patients to alternative treatments. Inform patients currently taking Ukoniq™ of the increased risk of death seen in the clinical trial and advise them to stop taking the medicine. In limited circumstances in which a patient may be receiving benefit from Ukoniq™, TG Therapeutics plans to make it available under expanded access.

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.

Member Information

Members should talk to their healthcare professionals about alternative treatments and stop taking Ukoniq™. It is best to dispose of unused Ukoniq™ using a drug take-back location. such as in a pharmacy. If one is not available, you can dispose of Ukoniq™ in your household trash by doing the following:

1. Mix the drug with an unappealing substance such as dirt, cat litter, or used coffee grounds (do not crush them).
2. Place the mixture in a container, such as a sealed plastic bag.

3. Throw away the container in the trash.
4. Remove all personal information from the prescription labels and throw the prescription bottles or packaging away or recycle them.

RxAdvance Response

RxAdvance is in the process of notifying members who have recently filled a prescription for this drug.