Optum Rx®

TG Therapeutics – Withdrawal of Ukoniq® (umbralisib)

- On June 1, 2022, the FDA announced that it has withdrawn its approval for Ukoniq (umbralisib) due to safety concerns.

- 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, TG Therapeutics announced it was voluntarily withdrawing Ukoniq from the market for the approved uses in MZL and FL.

Product Description	NDC#
Ukoniq (umbralisib) 200 mg tablets	73150-0200-12

- Health care providers should stop prescribing Ukoniq and switch patients to alternative treatments. Patients currently taking Ukoniq should be made aware of the increased risk of death seen in the clinical trial and advised 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 accsess.

- Patients should talk to their health care providers 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, but if one is not available, Ukoniq can be disposed of in household trash by doing the following:

  — Mix the medicine with an unappealing substance such as dirt, cat litter, or used coffee grounds; do not crush them.
  — Place the mixture in a container such as a sealed plastic bag.
  — Throw away the container in your home trash.
  — Delete all personal information on the prescription labels of empty medicine bottles or packaging, then throw away or recycle them.

- Patients should contact their physician or health care provider if they have experienced any problems that may be related to taking or using the withdrawn Ukoniq.

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