

## **FDA approval of lymphoma medicine Ukoniq (umbralisib) is withdrawn due to safety concerns**

*Possible increased risk of death outweighs the benefits*

This is an update to the [FDA Drug Safety Communication: FDA investigating possible increased risk of death with lymphoma medicine Ukoniq \(umbralisib\)](#) issued on February 3, 2022.

### **6-1-2022 FDA Drug Safety Communication**

Due to safety concerns, the U.S. Food and Drug Administration (FDA) has withdrawn its approval for the cancer medicine Ukoniq (umbralisib).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, we 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.

**Health care 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](#).

**Patients** should talk to your health care 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, but if one is not available, you can dispose of Ukoniq in your household trash by doing the following:

1. Mix the medicine 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 your home trash.
4. Delete all personal information on the prescription labels of empty medicine bottles or packaging, then throw away or recycle them.

We urge health care professionals and patients to report side effects involving medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Health care professionals, patients, and consumers can sign up for [email alerts](#) about Drug Safety Communications on medicines or medical specialties of interest to you.

**Related Information**

[National Cancer Institute: Lymphoma](#)

[The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective](#)

[Think It Through: Managing the Benefits and Risks of Medicines](#)