Important Drug Recall Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC22-056-CG
June 3, 2022

FDA announced that, 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 marginal zone lymphoma and follicular lymphoma.

RECOMMENDATIONS

1. 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.

2. 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:

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

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

4. 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

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Failure Ukoniq (umbralisib): Drug Safety Communication - FDA Approval of Lymphoma Medicine is Withdrawn Due to Safety Concerns

[Posted 06/01/2022]

AUDIENCE: Oncology, Patient, Health Professional, Pharmacy

ISSUE: Due to safety concerns, the FDA has withdrawn its approval for the cancer medicine Ukoniq (umbralisib).

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 marginal zone lymphoma and follicular lymphoma.

BACKGROUND: Ukoniq was approved to treat two specific types of lymphoma: marginal zone lymphoma and follicular lymphoma.

RECOMMENDATIONS:

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.

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FDA U.S. FOOD & DRUG ADMINISTRATION

Health care professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online.
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form, or submit by fax to 1-800-FDA-0178.

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