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Important Drug Safety Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC22-026-CG AMENDMENT
February 4, 2022

The FDA announced that it is investigating a possible increased risk of death with the cancer medicine Ukoniq (umbralisib) approved to treat two specific types of lymphomas, which are cancers that affect the body's immune system. The FDA determined that initial findings from a clinical trial evaluating Ukoniq to treat a related type of cancer found a possible increased risk of death in patients taking the medicine. Because of the seriousness of this safety concern and the similarities between the two types of cancer for which this drug is approved and the type of cancer that was studied in the clinical trial, the FDA is alerting patients and health care professionals that FDA is re-evaluating this risk against the benefits of Ukoniq for its approved uses.

RECOMMENDATIONS

1. Health care professionals should review their patients' progress on Ukoniq and discuss with them the risks and benefits of continuing Ukoniq in the context of other available treatments.

2. Patients should talk to their health care professionals about the risks and benefits of Ukoniq or any concerns they may have, including about possible alternative treatments.

3. Health care professionals, consumers 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.

4. Expect patients to visit your pharmacy asking for information on this safety issue and prepare your pharmacy staff on how to handle the situation.

MC-Rx Pharmacy Services Department

Call Box 4908, Caguas, PR 00726

FDA U.S. FOOD & DRUG ADMINISTRATION

Ukoniq (umbralisib): Drug Safety Communication - FDA Investigating Possible Increased Risk of Death with Lymphoma

[Posted 02/03/2022]

AUDIENCE: Oncology, Patient, Health Professional, Pharmacy

ISSUE: The FDA is investigating a possible increased risk of death with the cancer medicine Ukoniq (umbralisib) approved to treat two specific types of lymphomas, which are cancers that affect the body's immune system. The FDA determined that initial findings from a clinical trial evaluating Ukoniq to treat a related type of cancer found a possible increased risk of death in patients taking the medicine. Because of the seriousness of this safety concern and the similarities between the two types of cancer for which this drug is approved and the type of cancer that was studied in the clinical trial, the FDA is alerting patients and health care professionals that FDA is re-evaluating this risk against the benefits of Ukoniq for its approved uses.

The FDA is continuing to evaluate the results from the clinical trial called UNITY. The FDA may also hold a future public meeting to discuss these findings and explore the continued marketing of Ukoniq. The FDA has also suspended enrollment of new patients in other ongoing clinical trials of Ukoniq while the FDA continues to review the UNITY findings. The FDA will communicate our final conclusions and recommendations when the FDA has completed the review or has more information to share.

The FDA conducted an initial review of data from UNITY, a phase 3, randomized, controlled clinical trial in patients with chronic lymphocytic leukemia (CLL). The trial is evaluating Ukoniq in combination with a monoclonal antibody drug that targets a specific protein called CD20 compared to the control arm in which patients received standard treatment. The results showed a possible increased risk of death in patients receiving the combination of Ukoniq and the monoclonal antibody compared to the control arm. Those receiving the combination of Ukoniq and the monoclonal antibody also experienced more serious adverse events than those in the control arm. The UNITY trial was conducted in CLL patients, which is not an approved use but rather a use of this drug that is being studied; however, the FDA believes these findings have implications for its approved uses for marginal zone lymphoma (MZL) and follicular lymphoma (FL). In addition, clinical trials of other medicines in the same PI3 kinase inhibitor class as Ukoniq have shown similar safety concerns.

FDA U.S. FOOD & DRUG ADMINISTRATION

BACKGROUND: Ukoniq is a prescription medicine approved to treat adults with marginal zone lymphoma (MZL) when the disease has returned or it did not respond to prior treatment with at least one specific type of medicine. Ukoniq is also approved to treat adults with follicular lymphoma (FL) when the disease has returned or it did not respond to at least three prior treatments.

RECOMMENDATIONS:

Health care professionals should review their patients' progress on Ukoniq and discuss with them the risks and benefits of continuing Ukoniq in the context of other available treatments.

Patients should talk to their health care professionals about the risks and benefits of Ukoniq or any concerns you may have, including about possible alternative treatments.

Health care professionals, consumers 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.