COMMUNICATION

COM-2022-030

02
JUNE
2022

URGENT
PLEASE
REVIEW

Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug safety information.

U.S. Food & Drug Administration Publication Date:

06/01/2022

Drug Indication:

Ukoniq™ is for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen and relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy.

Safety Topic:

FDA approval of lymphoma medicine Ukoniq™ (umbralisib) is withdrawn due to safety concerns (possible increased risk of death outweighs the benefits).

Safety Concerns with Ukoniq™ (umbralisib)

It is for this reason that we are notifying you that on 06/01/2022 the US Food and Drug Administration (FDA) published a safety communication for the following product: Ukoniq™ (umbralisib).

Reason for Communication:

Back in February 2022 the FDA had published a safety alert stating that the agency was investigating a possible increased risk of death with the cancer drug Ukoniq™. The FDA had determined that initial findings from the UNITY-CLL clinical trial found a possible increased risk of death in patients taking this medication. The FDA was alerting patients and health care professionals that they were re-evaluating this risk against the benefits of Ukoniq™ for its approved uses.

Now in June 2022 the FDA has withdrawn its approval for Ukoniq™. The updated findings from the clinical trial mentioned above continued to show a possible increased risk of death in patients receiving umbralisib.

As a result, the agency has determined the risks of treatment with Ukoniq™ outweigh its benefits. Due to this determination, TG Therapeutics, the drug's manufacturer, is voluntarily withdrawing Ukoniq™ from the market.

Pharmacy Required Action:

Advise patients that they should talk to their health care professionals about alternative treatments and stop taking Ukoniq™. The FDA recommends disposing unused Ukoniq™ at a drug take-back location or, if a location is not available, the FDA recommends disposing Ukoniq™ in the household trash mixing it with an unappealing substance (e.g., dirt, used coffee grounds, cat litter) and placing it in a container such as a sealed plastic bag.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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REFERENCES:

1. U.S. Food and Drug Administration. (2022). FDA approval of lymphoma medicine Ukoniq (umbralisib) is withdrawn due to safety concerns. https://www.fda.gov/drugs/drug-safety-and-availability/fda-approval-lymphoma-medicine-ukoniq-umbralisib-withdrawn-due-safety-concerns
2. Ublituximab + TGR-1202 Compared to Obinutuzumab + Chlorambucil in Patients With Untreated and Previously Treated Chronic Lymphocytic Leukemia - Full Text View - ClinicalTrials.gov. (2022). https://clinicaltrials.gov/ct2/show/NCT02612311
3. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

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