COMMUNICATION

2022-015

03
MARCH
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:

02/03/2022

Drug Indication:

Ukoniq™ is indicated 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 or relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy.

Safety Topic:

The U.S. FDA is investigating possible increased risk of death with lymphoma medicine Ukoniq™ (umbralisib).

Increased Risk of Death with Ukoniq™

It is for this reason that we are notifying you that on 02/03/2022 the US Food and Drug Administration published a safety communication for the following product(s): Ukoniq™ (umbralisib).

Reason for Communication:

The U.S. FDA has determined that initial findings from a clinical trial (UNITY) evaluating Ukoniq™, in combination with a monoclonal antibody, to treat related type of cancer found a possible increased risk of death in patients taking this medication. 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 federal agency is alerting patients and health care professional that the 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. FDA may also hold a future public meeting to discuss these findings and explore the continued marketing of Ukoniq™. The agency has also suspended enrollment of new patients in other ongoing clinical trials while they continue to review the UNITY finding. They will communicate their final conclusions and recommendations when they have completed the review or have more information to share.

Pharmacy Required Action:

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician

Assess whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication.

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:
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2. Study to Assess the Efficacy and Safety of Ublituximab + Umbralisib With or Without Bendamustine and Umbralisib Alone in Patients With Previously Treated Non-Hodgkins Lymphoma. ClinicalTrials.gov. (2022). https://www.clinicaltrials.gov/ct2/show/NCT02793583
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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FRM-CL-000127-000

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