COMMUNICATION

COM-2022-039

04
July
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:

07/01/2022

Drug Indication:

Copiktra™, a PI3 kinase inhibitor, is indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies

Safety Topic:

FDA warns about possible increased risk of death and serious side effects with cancer drug Copiktra™ (duvelisib).

Possible Increased Risk of Death with Copiktra™

It is for this reason that we are notifying you that on 06/30/2022 the US Food and Drug Administration (FDA) published a safety communication for the following product: Copiktra™ (duvelisib).

Reason for Communication:

The US FDA is warning that results from the clinical trial, DUO trial, show a possible increased risk of death with Copiktra™ compared to the monoclonal antibody ofatumumab. In addition, the trial found that duvelisib was associated with a higher risk of serious side effects, including infections, diarrhea, inflammation of the intestines and lungs, skin reactions, and high liver enzyme levels in the blood. The rate of serious side effects, dose modifications, and deaths resulting from these side effects were also higher among patients who received Copiktra™.

The FDA is notifying the public of these risks and are continuing to evaluate the safety of Copiktra™. The agency will update the public once more information is available. These safety findings were similar for other drugs in the same PI3 kinase inhibitor class, which were discussed at an advisory committee meeting of non-FDA experts in April 2022. Of note, Secura Bio, Inc. had decided to voluntarily withdraw the indication of duvelisib for use in patients with follicular lymphoma back in December 2021.

Pharmacy Required Action:

Advise patients that they should not discontinue using the medication without contacting their healthcare provider.

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:
1. U.S. Food and Drug Administration. (2022). FDA warns about possible increased risk of death and serious side effects with cancer drug Copiktra (duvelisib). https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-possible-increased-risk-death-and-serious-side-effects-cancer-drug-copiktra
2. 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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