Important Drug Safety Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC22-063-CG
July 1st, 2022

FDA announced that, results from a clinical trial show a possible increased risk of death with Copiktra (duvelisib) compared to another medicine to treat a chronic blood cancer called leukemia and a lymphoma, a cancer found in the lymph nodes. The trial also found Copiktra 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.

RECOMMENDATIONS

1. Patients should talk to your health care professional about the risks and benefits of receiving Copiktra. Discuss any questions or concerns you may have, including about possible alternative treatments.

2. Health care professionals should consider the risks and benefits of continuing Copiktra in the context of other available treatments. Advise patients receiving Copiktra of the possible increased risk of death and higher risk of serious adverse events.

3. 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

T. (800) 377-1037
1267 Professional Pkwy, Gainesville, GA 30507
T. (787) 286-6032
Call Box 4908, Caguas, P.R. 00726
MC-Rx.com

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FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Warns About Possible Increased Risk of Death and Serious Side Effects with Cancer Drug Copiktra (duvelisib)

The U.S. Food and Drug Administration (FDA) is warning that results from a clinical trial show a possible increased risk of death with Copiktra (duvelisib) compared to another medicine to treat a chronic blood cancer called leukemia and a lymphoma, a cancer found in the lymph nodes. The trial also found Copiktra 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.

We are notifying the public of these risks and are continuing to evaluate the safety of Copiktra. We plan to hold a future public meeting to discuss the findings from the clinical trial and whether Copiktra should continue to be prescribed for patients. We will update the public when we have more information.

Patients should talk to your health care professional about the risks and benefits of receiving Copiktra. Discuss any questions or concerns you may have, including about possible alternative treatments.

Health care professionals should consider the risks and benefits of continuing Copiktra in the context of other available treatments. Advise patients receiving Copiktra of the possible increased risk of death and higher risk of serious adverse events.

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