Copiktra® (duvelisib) 15mg | 25mg capsules

FDA-Required REMS Safety Information
Important Update: Treatment-related Mortality

Dear Healthcare Provider:

The Food and Drug Administration (FDA) has required this safety notice as part of the COPIKTRA REMS (**R**isk **E**valuation and **M**itigation **S**trategy) to inform you about the following update to the Prescribing Information in July 2024.

Treatment-related Mortality

In a randomized controlled study in patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), treatment with COPIKTRA was associated with increased treatment-related mortality. With an extended follow-up period, median of 63 months, fatal adverse reactions occurred in 15% of patients treated with COPIKTRA and in 3% of patients treated in the comparator arm.

Advise patients that COPIKTRA has been associated with increased deaths due to side effects of therapy in a randomized study when compared to standard therapy. The main reason for death was infection.

Serious Toxicities

In addition, COPIKTRA can cause fatal and/or serious toxicities including **infections, diarrhea or colitis, cutaneous reactions, and pneumonitis**.

Counsel your patients on these risks. Provide your patients with the COPIKTRA Patient Safety Wallet Card available at www.COPIKTRAREMS.com.

Instruct your patients to seek immediate medical attention if they develop any of the following symptoms:

- **Symptoms of infection (e.g. fever, chills)**
- **New or worsening diarrhea, stool with mucus or blood, or abdominal pain**
- **New or worsening skin rash**
- **New or worsening respiratory symptoms including cough or difficulty breathing**

Please see the non-promotional Fact Sheet, reviewed by the FDA, and the full Prescribing Information for more detailed safety information. Additional copies of the Patient Safety Wallet Card, Fact Sheet, and other important information are available at: www.COPIKTRAREMS.com.

COPIKTRA is a kinase inhibitor indicated for the treatment of adult patients with:

- Relapsed or refractory CLL or SLL after at least two prior lines of systemic therapy.

Limitations of Use

COPIKTRA is not indicated or recommended for the treatment of any patients with CLL or SLL as initial or second line treatment due to an increased risk of treatment-related mortality.

Adverse Event Reporting

To report side effects during the use of COPIKTRA, contact Secura Bio, Inc. at **1-844-973-2872** and/or to FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

Sincerely,

Secura Bio, Inc.

SecuraBio

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