Copiktra™ (duvelisib)

FDA-REQUIRED REMS SAFETY INFORMATION

COPIKTRA has the following risks of fatal and/or serious toxicities:
- **Infections**
- **Diarrhea or Colitis**
- **Cutaneous Reactions**
- **Pneumonitis**

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 serious risks of COPIKTRA.

Serious Risks with Use of COPIKTRA

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 chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies.
- Relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies.
  This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Adverse Event Reporting

To report side effects during the use of COPIKTRA, contact Verastem Oncology at **1-877-779-8786** and/or to FDA at at www.fda.gov/medwatch or call 1-800-FDA-1088.

Sincerely,

Verastem Oncology

Verastem Oncology

Reference ID: 4324951 (FL), 4324975 (CLL)

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