Copiktra® (duvelisib) 15mg | 25mg capsules

FDA-Required REMS* Safety Information (Fact Sheet)

COPIKTRA has a BOXED WARNING for the following fatal and/or serious toxicities:

Treatment-related Mortality

- Treatment-related mortality occurred in 15% of patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in a randomized controlled study (N = 158), with extended follow-up, median of 63 months.
- In patients with relapsed or refractory CLL or SLL after at least two prior lines of systemic therapy in the randomized study, treatment-related mortality occurred in 14% (N = 93).
- The most common cause of treatment-related deaths were infections.
- COPIKTRA is not indicated and is not recommended for any patients in the initial or second-line treatment setting.

Infections

- Serious, including fatal (4%) infections occurred in 31% of patients receiving COPIKTRA 25 mg BID (N=442).
- The most common serious infections were pneumonia, sepsis, and lower respiratory infections.
- Treat infections prior to initiation of COPIKTRA. Advise patients to report any new or worsening signs and symptoms of infection.
  For Grade 3 or higher infection withhold COPIKTRA until infection has resolved. Resume COPIKTRA at the same or reduced dose.
- Serious, including fatal Pneumocystis jirovecii pneumonia (PJP) occurred in 1% of patients taking COPIKTRA. Provide prophylaxis for PJP during treatment with COPIKTRA. Following completion of COPKTRA treatment, continue PJP prophylaxis until the absolute CD4+ T cell count is greater than 200 cells/µL. Withhold COPIKTRA in patients with suspected PJP of any grade, and permanently discontinue if PJP is confirmed.
- CMV reactivation/infection occurred in 1% of patients taking COPIKTRA. Consider prophylactic antivirals during COPIKTRA treatment to prevent CMV infection including CMV reactivation. For clinical CMV infection or viremia, withhold COPIKTRA until infection or viremia resolves. If COPIKTRA is resumed, administer a reduced dose and monitor patients for CMV reactivation by PCR or antigen test at least monthly.

Diarrhea or Colitis

- Serious, including fatal (<1%), diarrhea or colitis occurred in 18% of patients receiving COPIKTRA 25 mg BID (N=442).
- Advise patients to report any new or worsening diarrhea.
- For non-infectious diarrhea or colitis, follow the guidelines below:
  - For patients presenting with mild or moderate diarrhea (Grade 1-2) (i.e. up to 6 stools per day over baseline) or asymptomatic (Grade 1) colitis:
    - Initiate supportive care with antidiarrheal agents as appropriate, continue COPIKTRA at the current dose, and monitor the patient at least weekly until the event resolves.
    - If the diarrhea is unresponsive to antidiarrheal therapy, withhold COPIKTRA and initiate supportive therapy with enteric acting steroids (e.g. budesonide). Monitor the patient at least weekly. Upon resolution of the diarrhea, consider restarting COPIKTRA at a reduced dose.
  - For patients presenting with abdominal pain, stool with mucus or blood, change in bowel habits, peritoneal signs, or with severe diarrhea (Grade 3) (i.e. > 6 stools per day over baseline) follow the guidelines below:
    - Withhold COPIKTRA and initiate supportive therapy with enteric acting steroids (e.g. budesonide) or systemic steroids. A diagnostic work-up to determine etiology, including colonoscopy, should be performed. Monitor at least weekly. Upon resolution of the diarrhea or colitis, restart COPIKTRA at a reduced dose.
    - For recurrent Grade 3 diarrhea or recurrent colitis of any grade, discontinue COPIKTRA.
  - Discontinue COPIKTRA for life-threatening diarrhea or colitis.

Cutaneous Reactions

- Serious, including fatal (<1%), cutaneous reactions occurred in 5% of patients receiving COPIKTA 25 mg BID (N=442).
- Fatal cases included drug reaction with eosinophilia and systemic symptoms (DRESS) and toxic epidermal necrolysis (TEN).
- Advise patients to report any new or worsening cutaneous reactions.
- Review all concomitant medications and discontinue any medications potentially contributing to the event.
- For patients presenting with mild or moderate (Grade 1-2) cutaneous reactions, continue COPIKTRA at the current dose, initiate supportive care with emollients, anti-histamines (for pruritus), or topical steroids, and monitor the patient closely.
- Withhold COPIKTRA for severe (Grade 3) cutaneous reaction until resolution. Initiate supportive care with steroids (topical or systemic) or anti-histamines (for pruritus). Monitor at least weekly until resolved. Upon resolution of the event, restart COPIKTRA at a reduced dose. Discontinue COPIKTRA if severe cutaneous reaction does not improve, worsens, or recurs.
- For life-threatening cutaneous reactions, discontinue COPIKTRA.
- In patients with SJS, TEN, or DRESS of any grade, discontinue COPIKTRA.

Pneumonitis

- Serious, including fatal (<1%), pneumonitis reactions occurred in 5% of patients receiving COPIKTRA 25mg BID (N=442).
- Withhold COPIKTRA in patients who present with new or progressive pulmonary signs and symptoms such as cough, dyspnea, hypoxia, interstitial infiltrates on a radiologic exam, or a decline by more than 5% in oxygen saturation, and evaluate for etiology. If the pneumonitis is infectious, patients may be restarted on COPIKTRA at the previous dose once the infection, pulmonary signs and symptoms resolve.
- For moderate non-infectious pneumonitis (Grade 2), treat with systemic corticosteroids, and resume COPIKTRA at a reduced dose upon resolution.
- If non-infectious pneumonitis recurs or does not respond to steroid therapy discontinue COPIKTRA.
- For severe or life-threatening non-infectious pneumonitis, discontinue COPIKTRA and treat with systemic steroids.

Indication

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.

***A REMS (Risk Evaluation and Mitigation Strategy)** is a program required by the FDA to manage known and potential serious risks associated with a drug product. FDA has determined that a REMS is necessary to inform healthcare providers that COPIKTRA can cause fatal and/or serious toxicities including treatment-related mortality, infections, diarrhea or colitis, cutaneous reactions, and pneumonitis.

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.

For the complete safety profile of COPIKTRA, please see the full Prescribing Information, available at www.COPIKTRAREMS.com.

SecuraBio

Secura Bio, Inc.
1995 Village Center Circle, Suite 128
Las Vegas, NV 89134

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