



## PURPOSE

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

The purpose of the COPIKTRA™ REMS is to mitigate the risk of fatal and serious toxicities including:

- **Infections**

○ Serious, including fatal (4%) infection occurred in 31% of patients receiving COPIKTRA 25 mg twice daily (N=442).

- **Diarrhea or Colitis**

○ Serious, including fatal (<1%), diarrhea or colitis occurred in 18% of patients receiving COPIKTRA 25 mg twice daily (N=442).

- **Cutaneous Reactions**

○ Serious, including fatal (<1%) cutaneous reactions occurred in 5% of patients receiving COPIKTRA 25 mg twice daily (N=442).

- **Pneumonitis**

○ Serious, including fatal (<1%) pneumonitis without an apparent infectious cause occurred in 5% of patients receiving COPIKTRA 25 mg twice daily (N=442).

For more detailed information on these risks, please see the [Fact Sheet](#).

## INDICATION

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.

Counsel patients using the COPIKTRA Patient Safety Wallet Card. Provide the COPIKTRA [Patient Safety Wallet Card](#) to your patients.

-----  
**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
-----

/s/  
-----

RICHARD PAZDUR  
09/24/2018