Generic Name:
Palbociclib, ribociclib, abemaciclib
Trade Name:
Ibrance, Kisqali, Verzenio
Company:
Pfizer, Novartis,
Notes:

FDA is warning that palbociclib, ribociclib, and abemaciclib?medications used to treat some patients with advanced breast cancers?may cause rare but severe inflammation of the lungs. The agency has approved new warnings about this risk to the prescribing information and package insert for the entire class of these cyclin-dependent kinase 4/6 (CDK 4/6) inhibitor medicines.

The overall benefit of CDK 4/6 inhibitors is still greater than the risks when used as prescribed, FDA noted.

Patients should notify their health professional right away if they have any new or worsening symptoms involving the lungs, as these symptoms may indicate a rare but life-threatening condition that can lead to death. Symptoms to watch for include difficulty or discomfort with breathing and shortness of breath while at rest or with low activity.

Patients should not stop taking their medication without first talking to their health professional. It is important to know that people respond differently to all medications depending on their health, the diseases they have, genetic factors, other medications they are taking, a many other factors. Specific risk factors to determine the likelihood of a particular person to experience severe lung inflammation when taking palbociclib, ribociclib, or abemaciclib have not been identified.

Health professionals should monitor patients regularly for pulmonary symptoms that may indicate interstitial lung disease (ILD) and/or pneumonitis. Signs and symptoms may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams in patients in whom infectious, neoplastic, and other causes have been excluded. Interrupt CDK 4/6 inhibitor treatment in patients who have new or worsening respiratory symptoms, and permanently discontinue treatment in patients with severe ILD and/or pneumonitis.

FDA reviewed CDK 4/6 inhibitors cases from completed and ongoing clinical trials undertaken by manufacturers and their postmarket safety databases that described ILD and pneumonitis. Across the entire drug class, there were reports of serious cases, including fatalities.

Medication Monitor Categories:
Alerts and Recalls