

October 1, 2019

**COM-2019-043**

Dear provider of healthcare services,

The United States Food and Drug Administration (FDA) is warning that the use of medications within the class of cyclin-dependent kinase 4/6 (CDK 4/6) inhibitors may cause rare but severe inflammation of the lungs. The FDA approved new warnings about this risk to the prescribing information and Patient Package Insert for the entire class of CDK 4/6 inhibitors. However, it is of note that the overall benefit of CDK 4/6 inhibitors is still greater than the risks when used as prescribed.

CDK 4/6 inhibitors currently FDA- approved are Ibrance™ (palbociclib), Kisqali™ (ribociclib), and Verzenio™ (abemaciclib). These medications are used for the treatment of advanced or metastatic breast cancer that has spread to other parts of the body.

**RECOMMENDATIONS FOR HEALTHCARE PROFESSIONALS**

Monitor patients regularly for pulmonary signs or symptoms indicative of interstitial lung disease (ILD) and/or pneumonitis (e.g. hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams in patients in whom infectious, neoplastic, or other causes have been excluded).

Interrupt CDK 4/6 inhibitor treatment in patients who have new or worsening respiratory symptoms.

Permanently discontinue the CDK 4/6 inhibitor in patients with severe ILD or pneumonitis.

Advise patients to immediately report new or worsening respiratory symptoms.

Encourage patients to read the Patient Package Insert they receive with their prescriptions.

Report adverse events to the FDA MedWatch program.

For additional information, please visit: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-rare-severe-lung-inflammation-ibrance-kisqali-and-verzenio-breast-cancer>

On PharmPix we are compromised with the health and wellness of our insured. It is our priority to offer high quality services and to promote practices for health promotion and diseases prevention. If you have any doubt or wish to have more information regarding this document, you can call us to 787-522-5252, extension 137.

Regards,

Clinical Department

Reference: FDA warns about rare but severe lung inflammation with Ibrance, Kisqali, and Verzenio for breast cancer. Fda.gov. Retrieved from <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-rare-severe-lung-inflammation-ibrance-kisqali-and-verzenio-breast-cancer>

