

Safety Alert

Oct. 2025

Abemaciclib – Risk of keratitis

EDA performs label update to include the following:

Undesirable effects

Eye Disorder: keratitis with frequency unknown

Background:

Keratitis is a medical condition that refers to **inflammation of the cornea**—the clear, dome-shaped outer layer at the front of your eye that covers the pupil and iris.

It can be a serious condition that may lead to complications, including permanent vision loss, if not treated promptly.

The common symptoms of keratitis include:

- Eye pain (often severe)
- Redness and irritation of the eye
- A sensation of a foreign object or "sand" in the eye
- Excessive tearing or other eye discharge
- Sensitivity to light
- Blurred or reduced vision
- Difficulty opening the eyelid due to pain or irritation
- A white spot on the cornea

Therapeutic Indication

- Early Breast Cancer
- Advanced or Metastatic Breast Cancer

Reference

EMA ([click Here](#))