

Xeljanz | Rinvoq | Olumiant

On February 25, 2019, the FDA sent Safety Announcement stating that a clinical study of Xeljanz showed an increased risk of blood clots in the lungs (pulmonary embolism) and death. 9/2019 FDA issued update for other drugs in the class (Rinvoq and Olumiant).

Another Safety announcement was made July 25, 2019, in which FDA announced the approved changes to the label, warning about increased risk of blood clots and of death with the 10mg twice daily dose, including adding a boxed warning.

On January 27, 2021, Pfizer announced data (and FDA followed up with Safety announcement on February 4, 2021) showing an increased risk for both Cancer and Major Cardiovascular Events.

Criteria

- Significant cardiovascular event requiring hospitalization while on drug
- Cancer (excluding skin cancer or lung cancer if smoker)
- PE, DVT or blood clot
- Injury at the time of usage or within one month

