COMMUNICATION

2021-042

02 September 2021

URGENT PLEASE REVIEW

Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug safety information.

U.S. Food & Drug Administration Publication Date:

09/01/2021

Drug Indication:

Psoriatic arthritis, rheumatoid arthritis, and ulcerative colitis

Safety Topic:

Risk of serious heart-related events, cancer, blood clots and death for JAK inhibitors that treat certain chronic inflammatory conditions

QUESTIONS

Call us at 787-522-5252-X-220

Access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Safety Notification Topic.

It is for this reason that we are notifying you that on 09/01/2021, the US Food and Drug Administration (FDA) published a safety communication for the following product(s): Xeljanz™/Xeljanz XR™ (tofacitinib), Olumiant™ (baricitinib) and Rinvoq™ (upadacitinib).

Reason for Communication:

After FDA completed a review of a large, randomized safety clinical trial, they concluded there is an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death with arthritis and ulcerative colitis medicines Xeljanz™ and Xeljanz XR™. Previously, this medication had a boxed warning for higher doses (10mg twice daily); nonetheless, with the results of this new study, the lower doses (5mg twice daily) proved to have an increased risk of blood clots and death.

The FDA is requiring revisions to the Boxed Warning for Xeljanz™/Xeljanz XR™ (tofacitinib), Olumiant™ (baricitinib) and Rinvoq™ (upadacitinib) to include information about the risks of serious heart-related events, cancer, blood clots, and death.

Pharmacy Required Action:

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician.

Assess whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Safety Communication Number 042 September 2021

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REFERENCES:

1. Serious heart events, cancer, blood clots for certain JAK inhibitors. U.S. Food and Drug Administration. (2021). Retrieved 2 September 2021, from https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-warnings-about-increased-risk-serious-heart-related-events-cancer-blood-clots-and-death.
2. Fda.gov. (2021). Retrieved 2 September 2021, from https://www.fda.gov/media/151936/download.