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Tofacitinib: Drug Safety Communication Update

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on February 25, 2019 the US Food and Drug Administration (FDA) published a communication notifying an increased risk of blood clots (in lungs) and death in patients with rheumatoid arthritis (RA) when using a specific dose of tofacitinib (Xeljanz, Xeljanz XR) according to a safety clinical trial. FDA is alerting the public because these findings were noticed when using a 10 mg twice daily dose in patients with RA. However, this dose is only approved in the dosing regimen for patients with **ulcerative colitis**, an inflammatory bowel disease affecting the colon.

In the ongoing safety trial, which will continue through 2019, patients are transitioning from 10 mg twice daily dose to the lower, **currently approved dose of 5 mg twice daily for RA**. It is important to notice that the FDA is currently working with the manufacturer (Pfizer) to evaluate other available safety information for this medication. The FDA statement included some important suggestions for health care professionals and patients regarding the use of tofacitinib.

Health Care Professionals	Patients

- Follow the recommendations in the tofacitinib prescribing information for the **specific condition**.
- Monitor signs and symptoms of **pulmonary embolism**.
	- Not stop or change the dose of tofacitinib without talking to the health care professional.
	- Seek medical attention if experience the following **symptoms**:
	  ○ Sudden shortness of breath or difficulty breathing
	  ○ Chest pain or back pain
	  ○ Coughing up blood
	  ○ Excessive sweating
	  ○ Clammy or bluish colored skin

For additional information visit:
https://www.fda.gov/downloads/Drugs/DrugSafety/UCM631989.pdf

Department of Clinical Pharmacy

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