# XELJANZ (TOFACITINIB)
# PRESCRIBER TREATMENT MAINTENANCE CHECKLIST
## (FOR USE DURING FOLLOW-UP VISITS FOR PATIENTS ON XELJANZ TREATMENT)

Patient: .....

Date: _ _ / _ _ / _ _ _ _

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Serious VTE events including pulmonary embolism (PE), some of which were fatal, and deep vein thrombosis (DVT) have been observed in patients taking tofacitinib. A dose dependent increased risk for VTE was observed in clinical study with tofacitinib, compared to TNF inhibitors.

In a randomised post authorisation safety study in patients with Rheumatoid Arthritis (RA) who were 50 years of age or older with at least one additional cardiovascular risk factor, an increased incidence of myocardial infarctions and malignancies (excluding non-melanoma skin cancer), particularly lung cancer and lymphoma, was observed with tofacitinib compared to TNF inhibitors.

Events of serious infections, cardiovascular risk (excluding myocardial infarction [MI]), MI, herpes zoster, tuberculosis (TB) and other opportunistic infections, malignancy (including lymphoma and lung cancer), all-cause mortality, gastrointestinal perforations, interstitial lung disease, and laboratory abnormalities have been reported in patients treated with tofacitinib in clinical studies.

Tofacitinib should only be used if no suitable treatment alternatives are available in patients:
- 65 years of age and older;
- patients with history of atherosclerotic cardiovascular disease or other cardiovascular risk factors (such as current or past long-time smokers);
- patients with malignancy risk factors (e.g. current malignancy or history of malignancy)

Patients should be closely monitored for any signs and symptoms, and laboratory abnormalities for an early identification of these risks.

**This treatment maintenance checklist intends to remind you of the risks associated with use of tofacitinib and the recommended tests during tofacitinib treatment.**

**During the treatment of tofacitinib, please check the following at each office visit:**

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| **For patients with Juvenile idiopathic arthritis (JIA) who have been taking tofacitinib for 18 weeks and have not shown clinical improvement, have you considered the following?**<br>Available data suggest that clinical improvement is observed within 18 weeks of initiation of treatment with tofacitinib. Continued therapy should be carefully reconsidered in a patient exhibiting no clinical improvement within this timeframe | Yes ☐ No ☐ |
| **Is the patient currently pregnant or does this patient intends to become pregnant?**<br>**Note the following:**<br>• Use of tofacitinib during pregnancy is contraindicated<br>• Women of childbearing potential should be advised to use effective contraception during treatment with tofacitinib and for at least 4 weeks after the last dose | Yes ☐ No ☐ |
| **Is this patient breastfeeding or does this patient intend to breast-feed?**<br>**Note the following:**<br>• Use of tofacitinib during breastfeeding is contraindicated | Yes ☐ No ☐ |
| **Is the patient over 65 years of age?**<br>**If Yes:**<br>**Have you considered alternative treatment considering the increased risk of serious infections, MI and malignancies and all cause mortality?**<br>**Note the following:**<br>In patients over 65 years of age, tofacitinib should only be used in these patients if no suitable treatment alternatives are available. | Yes ☐ No ☐<br><br>Yes ☐ No ☐ |
| **Is the patient over 65 years of age, a current or past long-time smoker or have a history of atherosclerotic cardiovascular disease or other cardiovascular risk factors?**<br>**If Yes:**<br>**Are there any suitable treatment alternatives available for the patient?**<br>**Note the following:**<br>Given the increased risk of Major Adverse Cardiovascular Events (including MI), tofacitinib should only be used in these patients if no suitable treatment alternatives are available. | Yes ☐ No ☐<br><br><br>Yes ☐ No ☐ |

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| **Is the patient over 65 years of age, a current or past long-time smoker or have other malignancy risk factors (e.g. current or history of malignancy other than a successfully treated non-melanoma skin cancer)?**<br>**If Yes:**<br>**Are there any suitable treatment alternatives available for the patient?**<br>**Note the following:**<br>Given the increased risk of malignancy, tofacitinib should only be used if no suitable treatment alternatives are available | Yes ☐ No ☐<br><br>Yes ☐ No ☐ |
| **Has the patient developed any risk factors for VTE?**<br>• **Note the following:** Tofacitinib should be used with caution in patients with known risk factors for VTE, regardless of indication and dosage.<br>• Refer to the prescriber brochure for the VTE risk factors<br>Promptly evaluate patients with signs and symptoms of VTE and discontinue tofacitinib in patients with suspected VTE, regardless of dose or indication | Yes ☐ No ☐ |
| **For patients with RA with known risk factors for VTE, have you performed testing of D-dimer levels after approximately 12 months of treatment and is D-dimer test result >2x ULN?**<br>If yes, do the clinical benefits outweigh the risks of treatment continuation with tofacitinib? | Yes ☐ No ☐<br><br>Yes ☐ No ☐ |
| **For patients with Ulcerative Colitis (UC) who have lost response to tofacitinib 5mg twice daily maintenance, have you considered the following:**<br>• For patients with UC who are not at increased risk for VTE, MACE and malignancy, tofacitinib 10 mg orally twice daily may be considered if the patient has failed to respond to alternative treatment options for ulcerative colitis such as tumour necrosis factor inhibitor (TNF inhibitor) treatment.<br>• Tofacitinib 10 mg twice daily for maintenance treatment is not recommended in patients with UC who have known VTE, major adverse cardiovascular events (MACE) and malignancy risk factors, unless there is no suitable alternative treatment available | Yes ☐ No ☐ |
| **Does this patient have any new onset signs of symptoms of infections?**<br>**Note the following:**<br>• Patients should be evaluated and tested for latent or active infection per applicable guidelines during administration of tofacitinib<br>• If a new infection develops during treatment, please take the following recommended actions:<br>o Interrupt tofacitinib treatment<br>o Prompt and complete diagnostic testing that is appropriate for an immunocompromised patient<br>o Appropriate antimicrobial therapy should be initiated<br>o Close monitoring of the patient and their neutrophil count | Yes ☐ No ☐ |
| **Does this patient have any new onset abdominal signs or symptoms?**<br>**Note the following:**<br>• Patients presenting with new onset abdominal signs and symptoms should be evaluated promptly for early identification of gastrointestinal perforation | Yes ☐ No ☐ |
| **Does this patient have any new onset or worsening of signs or symptoms of interstitial lung disease?**<br>**Note the following:**<br>• Caution is recommended in patients with a history of chronic lung disease as they may be more prone to infections. Events of interstitial lung disease (some of which had a fatal outcome) have been reported in patients treated with tofacitinib. | Yes ☐ No ☐ |
| **Has the haemoglobin level been monitored?**<br>**Note the following:**<br>• If less than or equal to 2 g/dL decrease and greater than or equal to 9.0 g/dL, maintain dose<br>• If greater than 2 g/dL decrease or less than 8.0 g/dL (confirmed by repeat testing), interrupt the administration of tofacitinib until haemoglobin values have normalised<br>• Haemoglobin should be monitored at baseline and after 4 to 8 weeks of treatment and every 3 months thereafter | Yes ☐ No ☐ |
| **Has liver enzyme testing been routinely performed?**<br>**Note the following:**<br>• Routine monitoring of liver tests and prompt investigation of the causes of liver enzyme elevations is recommended to identify potential cases of drug-induced liver injury.<br>• If drug-induced injury is suspected, the administration of tofacitinib should be interrupted until this diagnosis has been excluded. | Yes ☐ No ☐ |