Xeljanz®

(Tofacitinib)

PRESCRIBER TREATMENT CHECKLIST

I XELJANZ PRESCRIBER TREATMENT INITIATION CHECKLIST

Setting: ☐ Inpatient ☐ Outpatient **Patient:** ☐ new patient ☐ follow-up visit

Date:_____

Introduction

• XELJANZ® (tofacitinib citrate) is an inhibitor of Janus kinases (JAKs) approved by US Food and drug administration (FDA) & Saudi Food and Drug Authority (SFDA)

• XELJANZ® is an inhibitor of Janus kinases (JAKs), is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs).

• XELJANZ® should not be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine

This treatment initiation checklist intends to remind you of the risks associated with use of tofacitinib and the recommended tests before tofacitinib treatment.

Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis.

Events of serious infections including tuberculosis (TB) and other opportunistic infections, malignancy, gastrointestinal perforations, and laboratory abnormalities have been reported in RA patients treated with tofacitinib in clinical studies. Patients should be closely monitored for any signs and symptoms, and laboratory abnormalities for an early identification of these risks.

Prior to administration of tofacitinib to patients, please check the following:

Does this patient have any evidence of hepatic impairment (Child-Pugh A, B or C)? • Severe hepatic impairment (Child-Pugh C): Tofacitinib should not be used • Moderate hepatic impairment (Child-Pugh B): Tofacitinib dose should be reduced to 5 mg once daily • Mild hepatic impairment (Child-Pugh A): No dose adjustment is required	Yes ☐ No ☐
Does this patient have any evidence of renal impairment (based on creatinine clearance)? • Severe renal impairment (creatinine clearance <30 mL/min): Tofacitinib dose should be reduced to 5 mg once daily • Mild (creatinine clearance 50-80mL/min) or moderate renal impairment	Yes ☐ No ☐

(creatinine clearance 30-49 mL/min): No dose adjustment is required • Supplemental doses are not necessary in patients after dialysis	
Is this patient currently pregnant or does this patient intends to become pregnant? • Tofacitinib should not be used during pregnancy unless clearly necessary • 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? • Women should not breast-feed while being treated with tofacitinib	Yes ☐ No ☐
Is this patient currently taking any biological DMARDs or any potent immunosuppressants? • Tofacitinib should be avoided in combination with biological DMARDs and potent immunosuppressants	Yes ☐ No ☐
Does this patient have any active infections including localized infections? • Tofacitinib should not be initiated in patients with active tuberculosis (TB), serious infections, such as sepsis, or opportunistic infections. • The risks and benefits of treatment should be considered prior to initiating tofacitinib in patients: o with chronic or recurrent infections, o who have been exposed to tuberculosis, o with a history of a serious or an opportunistic infection, o who have resided or travelled in areas of endemic tuberculosis or endemic mycoses, o who have underlying conditions that may predispose them to infection	Yes ☐ No ☐
Has this patient been evaluated and tested for latent or active TB? • Patients should be evaluated and tested for latent or active TB prior to administration of tofacitinib • Patients with latent TB should be treated with standard antimycobacterial therapy before administering tofacitinib	Yes ☐ No ☐
Has anti-TB therapy been considered, particularly if this patient has a past history of latent or active TB? • Antituberculosis therapy should be considered prior to administration of tofacitinib in patients with a past history of latent or active TB in whom an	Yes ☐ No ☐

adequate course of treatment cannot be confirmed, and for patients with a negative test for latent TB, but who have risk factors for TB infection • Consultation with a healthcare professional with expertise in the treatment of TB is recommended to aid in the decision about whether initiating antituberculosis therapy is appropriate for an individual patient	
Has this patient been evaluated and screened for viral hepatitis in accordance with published guidelines? • The impact of tofacitinib on chronic viral hepatitis reactivation is unknown • Screening for viral hepatitis should be performed in accordance with clinical guidelines before starting therapy with tofacitinib	Yes ☐ No ☐
Does this patient have a medical history of diverticulitis? • Tofacitinib should be used with caution in patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis)	Yes ☐ No ☐
Does this patient have current or a medical history of malignancy? • The risks and benefits of treatment should be considered prior to initiating tofacitinib in patients with current or a history of malignancy	Yes ☐ No ☐
Have this patient's lymphocytes, neutrophils, and haemoglobin been measured? • Initiating treatment is not recommended in patients with: o Low lymphocyte count (<500 cells/mm^3) o Low absolute neutrophil count (<1000 cells/mm^3) o Low haemoglobin (<9 g/dL)	Yes ☐ No ☐
Have all of this patient's immunizations been brought up to date in agreement with current immunization guidelines? • It is recommended that all patients be brought up to date with all immunisations in agreement with current immunization guidelines prior to initiating tofacitinib therapy • The interval between live vaccinations and initiation of tofacitinib therapy should be in accordance with current vaccination guidelines regarding immunomodulatory agents. o Consistent with these guidelines, if live zoster vaccine is administered, it should only be administered to patients with a	Yes ☐ No ☐

	known history of chickenpox or those that are seropositive for varicella zoster virus. Vaccination should occur at least 2 weeks but preferably 4 weeks before initiating immunomodulatory agents such as tofacitinib.	

Discussion with your patients

Have you discussed the overall benefits and risks of tofacitinib with your patient?	Yes ☐ No ☐
Have you given the patient safety card to your patient?	Yes ☐ No ☐
Have you discussed the use of patient safety card with your patient?	Yes ☐ No ☐

II XELJANZ PRESCRIBER TREATMENT MAINTENANCE CHECKLIST

Setting: ☐Inpatient ☐ Outpatient **Patient:** ☐ new patient ☐ follow-up visit

Date:_____

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

Events of serious infections including tuberculosis (TB) and other opportunistic infections, malignancy, gastrointestinal perforations, and laboratory abnormalities have been reported in RA patients treated with tofacitinib in clinical studies. Patients should be closely monitored for any signs and symptoms, and laboratory abnormalities for an early identification of these risks.

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

Is this patient currently pregnant or does this patient intends to become pregnant? • Tofacitinib should not be used during pregnancy unless clearly necessary • 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 ☐
Does this patient have any new onset signs of symptoms of infections? • Patients should be evaluated and tested for latent or active infection per applicable guidelines during administration of tofacitinib • If a new infection develops during treatment, please take the following recommended actions: o Interrupt tofacitinib treatment o Prompt and complete diagnostic testing o Appropriate antimicrobial therapy should be initiated o Close monitoring of the patient	Yes ☐ No ☐

Does this patient have any new onset abdominal signs or symptoms? • Patients presenting with new onset abdominal signs and symptoms should be evaluated promptly for early identification of gastrointestinal perforation	Yes ☐ No ☐
What is the recent lymphocyte count? • If lymphocyte count below 500 cells/mm^3 (confirmed by repeated testing), discontinue tofacitinib **How often has lymphocyte count been monitored?** • Lymphocytes should be measured every 3 months during the treatment	Yes ☐ No ☐
What is the recent neutrophil count? • If the ANC is greater than 1000 cells/mm^3, maintain dose • If the ANC is 500–1000 cells/mm^3, interrupt dosing until ANC is >1000 cells/mm^3 • If the ANC is <500 cells/mm^3 (confirmed by repeat testing), discontinue treatment **How often has neutrophil count been monitored?** • Neutrophils should be measured at baseline, then after 4 to 8 weeks of treatment, and then every 3 months	Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐
What is the recent haemoglobin level? • If less than or equal to 2 g/dL decrease and greater than or equal to 9.0 g/dL, maintain dose • 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 **How often has haemoglobin level been monitored?** • Haemoglobin should be measured at baseline, then after 4 to 8 weeks of treatment, and then every 3 months	Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐
How often has lipid parameters been monitored? • Assessment of lipid parameters should be tested after 8 weeks following initiation of tofacitinib therapy. Patients should be managed according to clinical guidelines for the management of hyperlipidaemia.	Yes ☐ No ☐

Your treatment with… XELJANZ® (Tofacitinib Citrate)

Please report any adverse events through the following channels

1. The National Pharmacovigilance & Drug Safety Centre (NPC)
Fax: +966 112057662
Unified: 1999
Toll free phone: 8002490000
E-mail: npc.drug@sfda.gov.sa
Website: www.sfda.gov.sa/npc

Or

2. The Pharmacovigilance Department in Pfizer:
Email: SAU.AEReporting@Pfizer.com
Tel.: 012 22 93 633