XELJANZ®
(tofacitinib citrate)
5 mg tablets

Pfizer

PRESCRIBER TREATMENT INITIATION CHECKLIST

Patient: ☐ New patient ☐ Follow-up visit Date: .....

Introduction

XELJANZ (tofacitinib citrate) is an inhibitor of Janus kinases (JAKs) that has been granted a positive opinion by the EU Committee for Medicinal Products for Human Use (CHMP) for use in combination with methotrexate (MTX) in adult patients with moderate to severe active rheumatoid arthritis (RA) who have responded inadequately to, or who are intolerant to, one or more disease-modifying antirheumatic drugs. Tofacitinib can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate. The recommended posology is 5 mg administered twice daily.

Treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis. Events of serious infections, herpes zoster, tuberculosis (TB) and other opportunistic infections, malignancy, gastrointestinal perforations, interstitial lung disease, 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 early identification of these risks.

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

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

PREGNANCY AND LACTATION **IS THIS PATIENT CURRENTLY PREGNANT OR DOES THIS PATIENT INTEND TO BECOME PREGNANT?** • Use of tofacitinib during pregnancy is contraindicated • 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 BREASTFEED? • Use of tofacitinib during breastfeeding is contraindicated	YES ☐ NO ☐
MEDICAL HISTORY **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 50-80 mL/min) or moderate renal impairment (creatinine clearance 30-49 mL/min): No dose adjustment is required • Supplemental doses are not necessary in patients after dialysis	YES ☐ NO ☐
DOES THIS PATIENT HAVE ANY ACTIVE INFECTIONS INCLUDING LOCALISED INFECTIONS? • Tofacitinib must not be initiated in patients with active TB, serious infections, such as sepsis, or opportunistic infections • The risks and benefits of treatment should be considered prior to initiating tofacitinib in patients: - with recurrent infections - who have been exposed to TB - with a history of a serious or an opportunistic infection - who have resided or travelled in areas of endemic TB or endemic mycoses - who have underlying conditions that may predispose them to infection (e.g., history of chronic lung disease)	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 and per applicable guidelines during 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 who test negative for TB but who have a past history of latent or active TB and where an adequate course of treatment cannot be confirmed, or those who test negative but who have risk factors for TB infection	YES ☐ NO ☐

XELJANZ®
(tofacitinib citrate)
5 mg tablets

PRESCRIBER TREATMENT INITIATION CHECKLIST

• 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. Patients should be closely monitored for the development of signs and symptoms of TB, including patients who tested negative for latent TB infection prior to initiating therapy.	
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, patients with concomitant use of corticosteroids and/or NSAIDs).	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 (other than a successfully treated non-melanoma skin cancer) or when considering continuing tofacitinib in patients who develop a malignancy.	YES ☐ NO ☐
CONCOMITANT MEDICATIONS **IS THIS PATIENT CURRENTLY TAKING ANY BIOLOGICAL DMARDS OR ANY POTENT IMMUNOSUPPRESSANTS?** • Tofacitinib should be avoided in RA patients in combination with biological DMARDs such as tumour necrosis factor (TNF) antagonists, interleukin (IL)-1R antagonists, IL-6R antagonists, anti-CD20 monoclonal antibodies, selective co-stimulation modulators and potent immunosuppressants such as azathioprine, ciclosporine and tacrolimus because of the possibility of increased immunosuppression and increased risk of infection.	YES ☐ NO ☐
LAB MONITORING **HAVE THIS PATIENT£S LYMPHOCYTES, NEUTROPHILS, AND HAEMOGLOBIN BEEN MEASURED?** • Initiating treatment is not recommended in patients with: - Low lymphocyte count (<750 cells/mm^3) - Low absolute neutrophil count (<1000 cells/mm^3) - Low haemoglobin (<9 g/dL)	YES ☐ NO ☐
DOES THE PATIENT HAVE ABNORMAL ELEVATED ALANINE AMINOTRANSFERASE (ALT) OR ASPARTATE AMINOTRANSFERASE (AST)? • Caution should be exercised when considering initiation of tofacitinib treatment in patients with elevated ALT or AST	YES ☐ NO ☐
VACCINATION **HAVE ALL OF THIS PATIENT£S IMMUNISATIONS BEEN BROUGHT UP TO DATE IN AGREEMENT WITH CURRENT IMMUNISATION GUIDELINES?** • Prior to initiating tofacitinib it is recommended that all patients be brought up to date with all immunisations in agreement with current immunisation guidelines. It is recommended that live vaccines not be given concurrently with tofacitinib.The decision to use live vaccines prior to treatment should take into account the degree of immunocompetence of a given patient. • Prophylactic zoster vaccination should be considered in accordance with vaccination guidelines. Particular consideration should be given to patients with longstanding rheumatoid arthritis who have received two or more prior biological DMARDs. If live zoster vaccine is administered, it should only be administered to patients with a known history of chickenpox or those that are seropositive for varicella zoster virus (VZV). If the history of chickenpox is considered doubtful or unreliable, it is recommended to test for antibodies against VZV. • Vaccination with live vaccines should occur at least 2 weeks, but preferably 4 weeks, or in accordance with current vaccination guidelines regarding immunomodulatory agents such as tofacitinib.	YES ☐ NO ☐
Discussion with your patients: **HAVE YOU DISCUSSED THE OVERALL BENEFITS AND RISKS OF TOFACITINIB WITH YOUR PATIENT?** **HAVE YOU GIVEN THE PATIENT ALERT CARD TO YOUR PATIENT?** **HAVE YOU DISCUSSED THE USE OF THE PATIENT ALERT CARD WITH YOUR PATIENT?**	YES ☐ NO ☐ ☐ ☐ ☐ ☐