XELJANZ®
(tofacitinib citrate)

Pfizer

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

PRESCRIBER TREATMENT INITIATION CHECKLIST

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

Introduction

xELJANZ® (tofacitinib citrate) is an inhibitor of Janus kinases (JAKs) that was granted a marketing authorization in the EU (22 March 2017) 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.

XELJANZ has now also received marketing authorization in the EU for use in combination with MTX in adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or who have been intolerant to a prior DMARD therapy. The recommended posology is 5 mg administered twice daily.

Tofacitinib has also received marketing authorization in the EU for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent. The recommended dose for UC is 10 mg given orally twice daily for induction for 8 weeks and 5 mg given twice daily for maintenance. For patients who do not achieve adequate therapeutic benefit by week 8, the induction dose of 10 mg twice daily can be extended for an additional 8 weeks (16 weeks total), followed by 5 mg twice daily for maintenance. Tofacitinib induction therapy should be discontinued in any patient who shows no evidence of therapeutic benefit by week 16. For some patients, such as those who have failed prior tumour necrosis factor (TNF) antagonist therapy, consideration should be given to continuation of the 10 mg twice daily dose for maintenance in order to maintain therapeutic benefit. Patients who experience a decrease in response on tofacitinib 5 mg twice daily maintenance therapy may benefit from an increase to tofacitinib 10 mg administered twice daily. In patients who have responded to treatment with tofacitinib, corticosteroids may be reduced and/or discontinued in accordance with standard of care. Retreatment: if therapy is interrupted, restarting treatment with tofacitinib can be considered. If there has been a loss of response, reinduction with tofacitinib 10 mg twice daily may be considered. The treatment interruption period in clinical studies extended up to 1 year. Efficacy may be regained by 8 weeks of 10 mg twice daily therapy.

Treatment of RA, PsA, and UC patients should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of these respective conditions.

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 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 intends 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:

	YES	NO
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): - RA and PsA: Tofacitinib dose should be reduced to 5 mg once daily - UC: Dose should be reduced to 5 mg once daily when the indicated dose in the presence of normal hepatic function is 5 mg twice daily. Dose should be reduced to 5 mg twice daily when the indicated dose in the presence of normal hepatic function is 10 mg twice daily • Mild hepatic impairment (Child-Pugh A): No dose adjustment is required	☐	☐
DOES THIS PATIENT HAVE ANY EVIDENCE OF RENAL IMPAIRMENT (BASED ON CREATININE CLEARANCE)? • Severe renal impairment (creatinine clearance <30 mL/min): - RA and PsA: Tofacitinib dose should be reduced to 5 mg once daily - UC: Dose should be reduced to 5 mg once daily when the indicated dose in the presence of normal renal function is 5 mg twice daily. Dose should be reduced to 5 mg twice daily when the indicated dose in the presence of normal renal function is 10 mg twice daily. Patients with severe renal impairment should remain on a reduced dose even after haemodialysis. • Mild (creatinine clearance 50-80mL/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	☐	☐
IS THIS PATIENT CURRENTLY PREGNANT OR DOES THIS PATIENT INTENDS 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	☐	☐
IS THIS PATIENT BREASTFEEDING OR DOES THIS PATIENT INTEND TO BREAST-FEED? • Use of tofacitinib during breastfeeding is contraindicated	☐	☐

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	YES	NO
IS THIS PATIENT CURRENTLY TAKING ANY BIOLOGICS OR ANY POTENT IMMUNOSUPPRESSANTS? • Tofacitinib should be avoided in patients in combination with biologics such as tumour necrosis factor (TNF) antagonists, interleukin (IL)-1R antagonists, IL-6R antagonists, anti-CD20 monoclonal antibodies, IL-17 antagonists, IL-12/IL-23 antagonists, anti-integrins, selective co-stimulation modulators and potent immunosuppressants such as azathioprine, cyclosporine, 6-mercaptopurine, and tacrolimus because of the possibility of increased immunosuppression and increased risk of infection.	☐	☐
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)	☐	☐
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 antimycobacterialtherapy before administering tofacitinib	☐	☐
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 • 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	☐	☐
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)	☐	☐
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.	☐	☐
HAVE THIS PATIENT'S LYMPHOCYTES, NEUTROPHILS, AND HAEMOGLOBIN BEEN MEASURED? • Initiating treatment is not recommended in patients with: - Low absolute lymphocyte count (<750 cells/mm^3) - Low absolute neutrophil count (<1000 cells/mm^3) - Low haemoglobin (<9 g/dL)	☐	☐
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	☐	☐
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 pre-existing immunosuppression ina 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 prior to initiation of tofacitinib or in accordance with current vaccination guidelines regarding immunomodulatory medicinal products such as tofacitinib.	☐	☐
DISCUSSION WITH YOUR PATIENTS	YES	NO
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 patient alert card with your patient?	☐	☐

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