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 MAINTENANCE 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.

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 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 <u>during</u> the tofacitinib treatment.

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

	YES	NO
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	☐	☐
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: - Interrupt tofacitinib treatment - Prompt and complete diagnostic testing that is appropriate for an immunocompromised patient - Appropriate antimicrobial therapy should be initiated - Close monitoring of the patient	☐	☐

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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 ☐
DOES THIS PATIENT HAVE ANY NEW ONSET OR WORSENING OF SIGNS OR SYMPTOMS OF INTERSTITIAL LUNG DISEASE? • 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 ☐
WHAT IS THE RECENT LYMPHOCYTE COUNT (ALC)? • If lymphocyte count is between 500 and 750 cells/mm^3 (2 sequential values in this range on routine testing) tofacitinib dosing should be reduced or interrupted until ALC is greater than 750. For patients receiving tofacitinib 5 mg twice daily, dosing should be interrupted. For patients with UC receiving tofacitinib 10 mg twice daily, dosing should be reduced to tofacitinib 5 mg twice daily. • When ALC is greater than 750, resume tofacitinib as clinically appropriate. • If ALC is below 500 cells/mm^3 (confirmed by repeated testing within 7 days), discontinue tofacitinib	YES ☐ NO ☐
HOW OFTEN HAS LYMPHOCYTE COUNT BEEN MONITORED? • Lymphocytes should be measured at baseline and 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 (2 sequential values in this range on routine testing), reduce or interrupt dosing until ANC is >1000 cells/mm.^{3} For patients receiving tofacitinib 5 mg twice daily, dosing should be interrupted. For patients with UC receiving tofacitinib 10 mg twice daily, dosing should be reduced to tofacitinib 5 mg twice daily. • When ANC is greater than 1000 cells/mm^3, resume treatment as clinically appropriate • If the ANC is <500 cells/mm^3 (confirmed by repeat testing within 7 days), discontinue treatment	YES ☐ NO ☐
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 ☐
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	YES ☐ NO ☐
HAS THE HAEMOGLOBIN LEVEL BEEN MONITORED ROUTINELY (I.E. AT BASELINE, THEN AFTER 4 TO 8 WEEKS OF TREATMENT, AND THEN EVERY 3 MONTHS)?	YES ☐ NO ☐
HAVE LIPID PARAMETERS BEEN MONITORED ROUTINELY (I.E. AFTER 8 WEEKS FOLLOWING INITIATION OF TOFACITINIB THERAPY)?	YES ☐ NO ☐
HAS LIVER ENZYME TESTING BEEN ROUTINELY PERFORMED? • 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. • If drug-induced injury is suspected, the administration of tofacitinib should be interrupted until this diagnosis has been excluded.	YES ☐ NO ☐

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