XELJANZ®
(tofacitinib citrate)
5 mg tablets

PRESCRIBER TREATMENT MAINTENANCE 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.

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 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 the tofacitinib treatment.

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

	YES	NO
MONITORING PREGNANCY **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.	☐	☐
MONITORING SIGNS AND SYMPTOMS **DOES THIS PATIENT HAVE ANY NEW ONSET SIGNS OR 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	☐	☐
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.	☐	☐
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.	☐	☐
LAB MONITORING **WHAT IS THE RECENT LYMPHOCYTE COUNT?** • If lymphocyte count is between 500 and 750 cells/mm^3 (2 sequential values in this range on routine testing) tofacitinb dosing should be interrupted until lymphocyte is greater than 750. When lymphocyte is greater than 750, resume tofacitinib 5 mg twice daily. • If lymphocyte count is below 500 cells/mm^3 (confirmed by repeated testing), discontinue tofacitinib	☐	☐
HOW OFTEN HAS LYMPHOCYTE COUNT BEEN MONITORED? • Lymphocytes should be measured at baseline and every 3 months during the treatment	☐	☐
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	☐ ☐ ☐	☐ ☐ ☐

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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 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 ☐