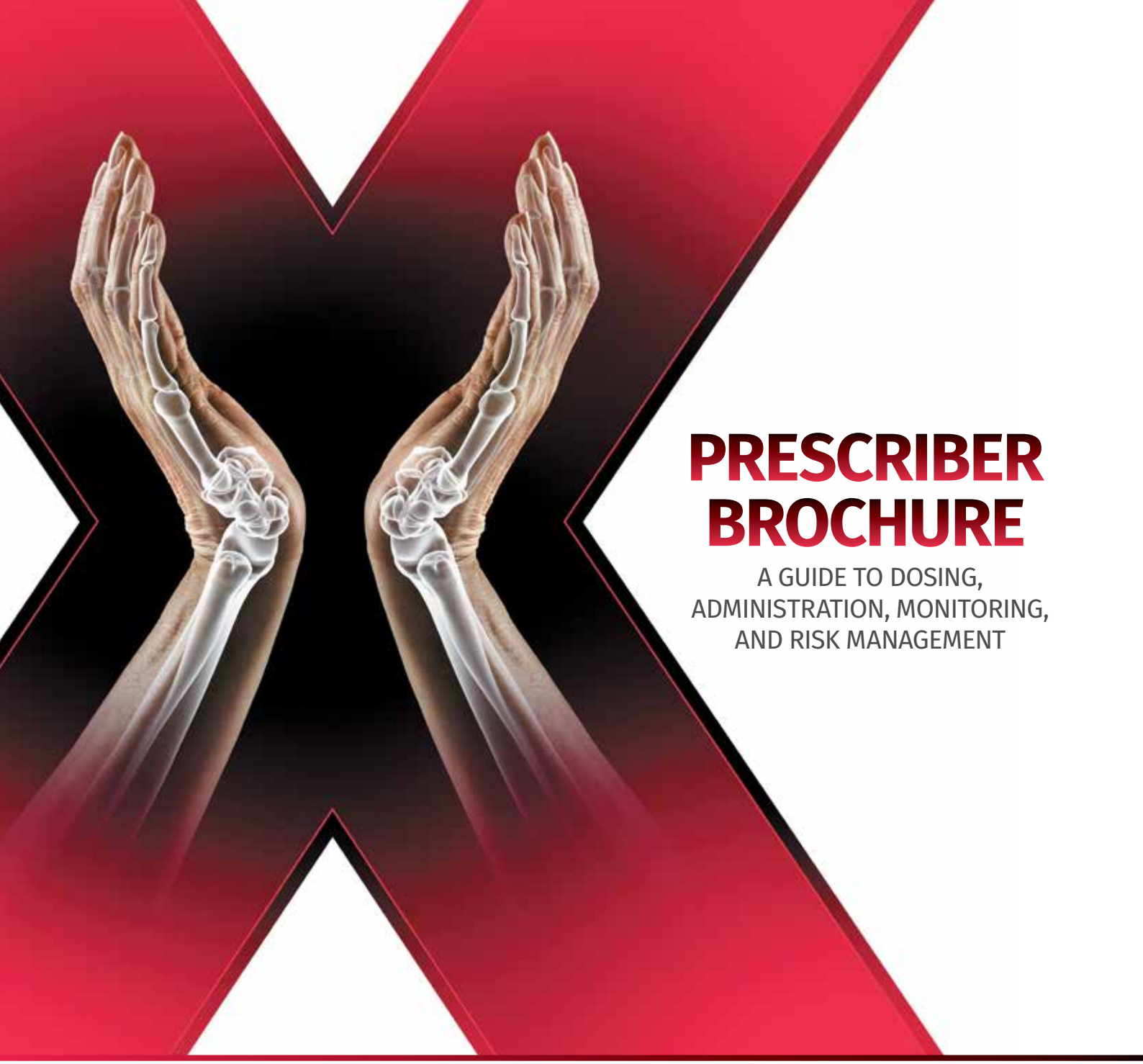

PRESCRIBER BROCHURE

A GUIDE TO DOSING, ADMINISTRATION, MONITORING, AND RISK MANAGEMENT

XELJANZ®
(tofacitinib citrate)

Version: 3.2
Date of approval: 03/2020

PRESCRIBER BROCHURE

This Prescriber Brochure intends to provide guidance on tofacitinib to the prescribing physicians with respect to therapeutic indications, dosing and administration including considerations for administration, instruction on monitoring laboratory parameters, precautions and warnings, patient counseling, reporting of adverse events, and a summary of the risk management plan.

▼ 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.

Version: 3.2 Date of approval: 03/2020

A guide to dosing, administration, monitoring, and risk management

Therapeutic indications

Rheumatoid arthritis

XELJANZ, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying antirheumatic drugs. XELJANZ can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate.

Psoriatic arthritis

XELJANZ in combination with MTX is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying anti-rheumatic drug (DMARD) therapy.

Ulcerative colitis

XELJANZ is indicated 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.

Posology and method of administration

RA

The recommended posology for RA is 5 mg film-coated tablets, administered orally twice daily. This should not be exceeded.

Prolonged release formulation (RA)

For RA, the recommended dosage of the 11 mg prolonged release tablet is orally once daily, which should not be exceeded. Patients treated with XELJANZ 5mg film coated tablets orally twice daily may be switched to XELJANZ 11 mg prolonged release tablets once daily on the day following the last dose of XELJANZ 5mg tablets. XELJANZ 11 mg prolonged release once daily has demonstrated pharmacokinetic equivalence to XELJANZ 5mg film coated tablets twice daily.

PsA

The recommended posology for PsA is 5 mg film-coated tablets administered orally twice daily. This should not be exceeded.

UC

Induction treatment for UC (weeks 0 through week 8, with extension to week 16 as necessary)

The recommended dose for UC is 10 mg film coated tablets given orally twice daily for induction for 8 weeks. For patients who do not achieve adequate therapeutic benefit by week 8, the induction dose of 10 mg film coated tablets twice daily can be extended for an additional 8 weeks (16 weeks total), followed by 5 mg film coated tablets twice daily for maintenance. XELJANZ induction therapy should be discontinued in any patient who shows no evidence of therapeutic benefit by week 16

Maintenance treatment for UC (post induction period)

The recommended dose for maintenance treatment is tofacitinib 5 mg film coated tablets given orally twice daily.

Tofacitinib 10 mg film coated tablets twice daily for maintenance treatment is not recommended in patients with UC who have known venous thromboembolism (VTE) risk factors, unless there is no suitable alternative treatment available.

For patients with UC who are not at increased risk for VTE tofacitinib 10 mg film coated tablets orally twice daily may be considered if the patient experiences a decrease in response on tofacitinib 5 mg film coated tablets twice daily and failed to respond to alternative treatment options for ulcerative colitis such as tumour necrosis factor inhibitor (TNF inhibitor) treatment. Tofacitinib 10 mg film coated tablets twice daily for maintenance treatment should be used for the shortest duration possible. The lowest effective dose needed to maintain response should be used.

In patients who have responded to treatment with XEJLANZ, corticosteroids may be reduced and/or discontinued in accordance with standard of care.

Retreatment in UC

If therapy is interrupted, restarting treatment with XELJANZ may be considered. If there has been a loss of response, reinduction with XELJANZ 10 mg film coated tablets 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 film coated tablets twice daily therapy.

XELJANZ 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.

XELJANZ should be avoided in combination with biologics and potent immunosuppressants because of the possibility of increased immunosuppression and increased risk of infection.

XELJANZ dose should be reduced by half in patients receiving potent inhibitors of cytochrome (CYP) P450 3A4 (e.g., ketoconazole) and in patients receiving one or more concomitant medicinal products that result in both moderate inhibition of CYP3A4 as well as potent inhibition of CYP2C19 (e.g., fluconazole) as follows:

- XELJANZ dose should be reduced to 5 mg once daily in patients receiving 5 mg twice daily.
- XELJANZ dose should be reduced to 5 mg once daily in patients receiving 11 mg prolonged release once daily (indicated for RAXELJANZ dose should be reduced to 5 mg twice daily in patients with UC receiving 10 mg twice daily.

Considerations for administration

Contraindications

- Hypersensitivity to the active substance(s) or to any of the excipients listed in Summary of Product Characteristics (SmPC)
- Active tuberculosis (TB) or other severe infections such as sepsis or opportunistic infections
- Severe hepatic impairment
- Pregnancy and lactation

Prior to administering XELJANZ

- Discuss the risks with patients using the **patient alert card** and **XELJANZ treatment initiation checklist** (see enclosed checklist for more details).
- Use with caution in patients with VTE risk factors
- Consider the risk and benefits of XELJANZ treatment carefully in patients who are at higher risk of developing serious infections including 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, such as diabetes mellitus.
  - Who are over 65 years of age
  - In patients over 65 years of age tofacitinib should only be considered if no suitable alternative treatment is available.
- Evaluate and test the patient for latent or active TB infection. Patients with latent TB should be treated with standard antimycobacterial therapy before administering XELJANZ.
- All patients should be brought up to date with all immunisations in agreement with current immunisation guidelines. Viral reactivation and cases of herpes virus reactivation (e.g., herpes zoster) were observed in clinical studies with XELJANZ. The risk of herpes zoster appears to be higher in Japanese and Korean patients treated with XELJANZ.
- Screening for viral hepatitis should be performed in accordance with clinical guidelines.
- Consider the risks and benefits of XELJANZ treatment prior to initiating therapy in patients with current or a history of malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing XELJANZ in patients who develop a malignancy
- Check patients' laboratory parameters including lymphocytes, neutrophils, haemoglobin, lipids, and hepatic enzymes. 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)

Patients treated with XELJANZ should be given a patient alert card. An adequate supply will be provided to prescribers for distribution to patients (through Pfizer local country office distribution channels). Additional copies can be downloaded via the prescriber website (see section Risk Communication for more details). **Patients should be advised to keep this card with them for at least 2 months after taking the last dose of XELJANZ.**

Monitoring of laboratory parameters:

Laboratory parameters	Routine Monitoring	Laboratory value	Recommended Actions
Lymphocytes (ALC)	At baseline, then every 3 months	Greater than or equal to 750 cells/mm^3	Dose should be maintained
		Between 500 and 750 cells/mm^3 (confirmed by repeat testing	Dosing should be reduced or interrupted until lymphocyte count is greater than 750 cells/mm^3 For patients receiving XELJANZ 5 mg twice daily, or 11 mg prolonged release once daily, dosing should be interrupted. For patients with UC receiving XELJANZ 10 mg twice daily, dosing should be reduced to XELJANZ 5 mg twice daily. When ALC is greater than 750, resume treatment as clinically appropriate.
		Less than 500 cells/mm^3 (confirmed by repeat testing)	Dosing should be discontinued.
Neutrophils (ANC)	At baseline, after 4 to 8 weeks of treatment, and then every 3 months	ANC greater than 1000 cells/mm^3	Dose should be maintained
		ANC 500–1000 cells/mm^3	For persistent decreases in this range, reduce or interrupt dosing until ANC is greater than 1000 cells/mm^3. For patients receiving XELJANZ 5 mg twice daily, or 11 mg prolonged release once daily, dosing should be interrupted. For patients with UC receiving XELJANZ 10 mg twice daily, dosing should be reduced to XELJANZ 5 mg twice daily. When ANC is greater than 1000 cells/mm^3 resume treatment as clinically appropriate.

Laboratory parameters	Routine Monitoring	Laboratory value	Recommended Actions
		ANC less than 500 cells/ mm^3	Dosing should be discontinued
Haemoglobin	At baseline, after 4 to 8 weeks of treatment, and then every 3 months	Less than or equal to 2 g/ dL decrease and greater than or equal to 9.0 g/dL	Dose should be maintained
		Greater than 2 g/dL decrease or less than 8.0 g/dL (confirmed by repeat testing)	Interrupt dosing until haemoglobin values have normalised
Lipids	After 8 weeks following initiation of therapy	NA	Managed according to clinical guidelines for the management of hyperlipidaemia
Liver enzymes	Routine monitoring	NA	Following initiation, 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
ALC=absolute lymphocyte count; ANC=absolute neutrophil count; NA=not applicable			

Special warnings and precautions for use

Combination with other therapies

XELJANZ has not been studied and its use should be avoided in patients in combination with biologics such as TNF antagonists, IL-1R antagonists, IL-6R antagonists, anti-CD20 monoclonal antibodies, IL-17 antagonists, IL-12/IL-23 antagonists, anti-integrins, and selective co-stimulation modulators and potent immunosuppressants such as azathioprine, 6-mercaptopurine, cyclosporine and tacrolimus because of the possibility of increased immunosuppression and increased risk of infection.

There is a higher incidence of adverse events for the combination of XELJANZ plus MTX versus XELJANZ as monotherapy in RA clinical trials.

Venous thromboembolism (VTE)

Serious VTE events including pulmonary embolism (PE), some of which were fatal, and deep vein thrombosis (DVT), have been observed in patients taking XELJANZ. VTE was observed at an increased and dose dependent incidence in patients treated with XELJANZ compared to TNF inhibitors. The majority of these events were serious and some cases of PE resulted in death.

XELJANZ should be used with caution in patients with known risk factors for VTE, regardless of indication and dosage.

VTE risk factors include:
- previous VTE,
- patients undergoing major surgery,
- immobilisation,
- myocardial infarction (within previous 3 months),
- heart failure,
- use of combined hormonal contraceptives or hormone replacement therapy,
- inherited coagulation disorder,
- malignancy.

Additional VTE risk factors such as age, obesity (BMI ≥30), diabetes, hypertension, smoking status should also be considered. Patients should be re-evaluated periodically during tofacitinib treatment to assess for changes in VTE risk.

For further guidance on VTE risk factors, please visit the Euopean Society of Cardiology guidelines for diagnosis and management of acute pulmonary embolism: https://doi.org/10.1093/eurheartj/ehz405

XELJANZ 10 mg film coated tablets twice daily for maintenance treatment is not recommended in patients with UC who have known VTE risk factors, unless there is no suitable alternative treatment available.

Patients should be advised on potential symptoms of VTE and to seek immediate medical attention if they experience these symptoms. Promptly evaluate patients with signs and symptoms of VTE and discontinue XELJANZ in patients with suspected VTE, regardless of dose or indication.

Rheumatoid arthritis:

In an interim analysis of a large, ongoing, randomised active-controlled post-authorisation safety surveillance study of rheumatoid arthritis patients who were 50 years of age and older and had at least one cardiovascular (CV) risk factor (Study ORAL Surveillance (A3921133)), VTE was observed at an increased and dose-dependent incidence in patients treated with tofacitinib compared to TNF inhibitors. The majority of these events were serious and some cases of PE resulted in death.

The incidence rates (95% CI) for PE for tofacitinib 10 mg twice daily, tofacitinib 5 mg twice daily, and TNF inhibitors were 0.54 (0.32-0.87), 0.27 (0.12-0.52), and 0.09 (0.02-0.26) patients with events per 100 patient-years, respectively. Compared with TNF inhibitors, the hazard ratio (HR) for PE was 5.96 (1.75-20.33) and 2.99 (0.81-11.06) for tofacitinib 10 mg twice daily and tofacitinib 5 mg twice daily, respectively.

In a subgroup analysis in patients with VTE risk factors in the above-mentioned study, the risk for PE was further increased. Compared with TNF inhibitors, the HR for PE was 9.14 (2.11-39.56) for tofacitinib 10 mg twice daily and 3.92 (0.83-18.48) for tofacitinib 5 mg twice daily.

The incidence rates (95% CI) for DVT for tofacitinib 10 mg twice daily, 5 mg twice daily, and TNF inhibitors were 0.38 (0.20 0.67), 0.30 (0.14 0.55), and 0.18 (0.07 0.39) patients with events per 100 patient years, respectively. Compared with TNF inhibitors, the HR for DVT with tofacitinib 10 mg twice daily was 2.13 (0.80 5.69), and for 5 mg twice daily the HR was 1.66 (0.60 4.57)

Completed randomised studies in RA

In studies of 6-, 12-, or 24-month duration (in which patients were not required to be 50 years or older or have at least one CV risk factors), the rate of PE in the 5 mg twice daily and 10 mg twice daily tofacitinib groups was 0.12 (95% CI 0.02 – 0.34) and 0.15 (0.03 – 0.44) patients with events per 100 patient-years, respectively. The rate of DVT in the 5 mg twice daily and 10 mg twice daily tofacitinib groups was 0.15 (95% CI 0.04 – 0.40) and 0.10 (0.01 – 0.36) patients with events per 100 patient-years, respectively.

Ulcerative colitis:

In the UC ongoing extension trial, cases of PE and DVT have been observed in patients using tofacitinib 10 mg twice daily and with underlying VTE risk factor(s).

Serious infections

Serious and sometimes fatal infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens have been reported in patients receiving tofacitinib.

The most common serious infections reported with XELJANZ were pneumonia, cellulitis, herpes zoster, urinary tract infection, diverticulitis, and appendicitis. Among opportunistic infections, TB and other mycobacterial infections, cryptococcus, histoplasmosis, oesophageal candidiasis, multidermatomal herpes zoster, cytomegalovirus, BK virus infections and listeriosis were reported with XELJANZ. Some patients have presented with disseminated rather than localised disease, and patients were often taking concomitant immunomodulating agents such as MTX or corticosteroids which, in addition to rheumatoid arthritis or psoriatic arthritis, may predispose them to infections. Other serious infections that were not reported in clinical studies may also occur (e.g., coccidioidomycosis). The risk of opportunistic infections is higher in Asian geographic regions.

Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with XELJANZ. Treatment must be interrupted if a patient develops a serious infection, an opportunistic infection, or sepsis. A patient who develops a new infection during treatment with XELJANZ should undergo prompt and complete diagnostic testing appropriate for an immunocompromised patient, appropriate antimicrobial therapy should be initiated, and the patient should be closely monitored.

Caution is recommended when XELJANZ treatment is used in the following patients:

- Elderly and diabetic patients given there is a higher incidence of infections in general
- Patients with a history of chronic lung disease as they may be more prone to infections.
- Patients with lymphopenia

In patients over 65 years of age, XELJANZ should only be considered if no suitable alternative treatment is available due to the increased risk of serious infections observed in Study ORAL Surveillance.

Tuberculosis

The risks and benefits of treatment should be considered prior to initiating XELJANZ in patients:

- who have been exposed to TB
- who have resided or travelled in areas of endemic TB or endemic mycoses

Patients should be evaluated and tested for latent or active infection prior to and per applicable guidelines during administration of XELJANZ.

Viral reactivation

Viral reactivation and cases of herpes virus reactivation (e.g., herpes zoster) were observed in clinical studies with XELJANZ. In patients treated with XELJANZ, the incidence of herpes zoster appears to be increased in:

- Japanese and Korean patients.
- Patients with an absolute lymphocyte count (ALC) less than 1000 cells/mm.3
- Patients with long standing RA who have previously received two or more biologic DMARDs.
- Patients with UC treated with 10 mg film coated tablets twice daily.

Malignancies and lymphoproliferative disorder [Excluding Non-melanoma Skin Cancer (NMSC)]

The risks and benefits of XELJANZ treatment should be considered prior to initiating therapy in patients with current or a history of malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing XELJANZ in patients who develop a malignancy. The possibility exists for XELJANZ to affect host defences against malignancies.

Lymphomas have been observed in patients treated with XELJANZ. Patients with RA, particularly those with highly active disease may be at a higher risk (up to several-fold) than the general population for the development of lymphoma. The role of XELJANZ in the development of lymphoma is uncertain.

Other malignancies were observed in clinical studies and the post-marketing setting, including, but not limited to, lung cancer, breast cancer, melanoma, prostate cancer, and pancreatic cancer.

The effect of XELJANZ on the development and course of malignancies is not known.

Non-melanoma skin cancer

NMSCs have been reported in patients treated with XELJANZ. The risk of NMSC may be higher in patients treated with XELJANZ 10 mg twice daily than in patients treated with 5 mg twice daily. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

Interstitial lung disease

Events of interstitial lung disease (some of which had a fatal outcome) have been reported in patients treated with XELJANZ in RA clinical trials and in the post-marketing setting although the role of Janus kinase (JAK) inhibition in these events is not known. Asian RA patients are known to be at higher risk of interstitial lung disease, thus caution should be exercised in treating these patients.

Gastrointestinal perforations

Events of gastrointestinal perforation have been reported in clinical trials although the role of Janus- kinase inhibition in these events is not known.

XELJANZ should be used with caution in patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis and patients with concomitant use of corticosteroids and/or nonsteroidal anti-inflammatory medicinal products). Patients presenting with new onset abdominal signs and symptoms should be evaluated promptly for early identification of gastrointestinal perforation.

Vaccination

- Prior to initiating XELJANZ 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 XELJANZ. The decision to use live vaccines prior to XELJANZ treatment should take into account the pre-existing immunosuppression in 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 prior to initiation of XELJANZ or in accordance with current vaccination guidelines regarding immunomodulatory medicinal products.

Use in Special Populations

Patients with renal impairment

- No dose adjustment is required in patients with mild (creatinine clearance 50-80 mL/min) or moderate renal impairment (creatinine clearance 30-49 mL/min).
- Severe renal impairment (creatinine clearance <30 mL/min): 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. or 11 mg prolonged release once daily (indicated in RA). 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 in patients with UC. Patients with severe renal impairment should remain on a reduced dose even after haemodialysis.

Patients with hepatic impairment

- No dose adjustment is required in patients with mild hepatic impairment (Child Pugh A).
- Moderate hepatic impairment (Child Pugh B): 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. or 11 mg prolonged release once daily (indicated in RA). 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 in patients with UC.
- XELJANZ should not be used in patients with severe hepatic impairment (Child Pugh C).

Pediatric patients

The safety and efficacy of XELJANZ in children aged from 0 to less than 18 years of age have not yet been established. No data are available.

Pregnancy and lactation

- Use of XELJANZ during pregnancy is contraindicated.
- Use of XELJANZ during breastfeeding is contraindicated.

Women of childbearing potential

- Women of childbearing potential should be advised to use effective contraception during treatment with XELJANZ and for at least 4 weeks after the last dose.

FOR MORE DETAILS ON PRESCRIBING XELJANZ, PLEASE REFER TO THE SUMMARY OF PRODUCT CHARACTERISTICS.

Patient Counseling

It is important for you to discuss the risks associated with use of XELJANZ with your patients, and in applicable instances, with their caregivers.

A patient alert card has been developed to help patients understand the risks associated with XELJANZ and remind them to seek immediate medical attention if they experience any listed signs and symptoms.

It is important for physicians to:

- provide the patient alert card to each patient who is prescribed with XELJANZ.
- remind patients to use the patient alert card.
- discuss the risks with each patient and ensure patient understanding of the treatment potential risks.
- ensure patients to carry the patient alert card with them, particularly when they visit doctors' office and/or the emergency room.

You should remind patients to seek immediate medical attention if they experience any of the following signs and symptoms.

- Sudden shortness of breath or difficulty breathing, chest pain or pain in upper back, swelling of the leg or arm, leg pain or tenderness, or redness or discoloration in the leg or arm while taking XELJANZ, as these may be signs of a clot in the lungs or veins.
- Experience possible symptoms of allergic reactions such as chest tightness, wheezing, severe dizziness or light-headedness, swelling of the lips, tongue or throat, itching or skin rash when taking XELJANZ, or soon after taking XELJANZ.
- Develop symptoms of an infection, such as fever, persistent cough, weight loss, or excessive tiredness.
- Develop symptoms of herpes zoster, such as painful rash or blisters.
- Have been in close contact with a person with TB.

- Notice any new growth on the skin or any changes in existing moles or spots.
- Develop symptoms of interstitial lung diseases, such as shortness of breath
- Develop abdominal signs and symptoms such as stomach pain, abdominal pain, blood in stool, or any change in bowel habits with fever.
- Develop yellow skin, nausea, or vomiting.
- Are due to receive any vaccine. Patients should not receive certain types of vaccines while taking XELJANZ.
- Become pregnant or plan on becoming pregnant.

To order more copies of the patient alert card, please call Pfizer's Local Representative, Vivian Corporation Ltd.: 00356 22588600 or visit the website: **www.tofacitinib-rmp.com.mt**

Reporting of Adverse Events

Reporting of Adverse Events

If you become aware of any suspected adverse reactions in association with use of XELJANZ, please report the event promptly to

ADR Reporting

www.medicinesauthority.gov.mt/adrportal

Malta Medicines Authority

Sir Temi Żammit Buildings,

Malta Life Sciences Park,

San Ġwann, SĠN 3000,

Malta Website: www.medicinesauthority.gov.mt/adrportal

e-mail: postlicensing.medicinesauthority@gov.mt

Also, please contact

Pfizer Hellas S.A.

Medical Information at +30 210 67 85 800.

Local Representative:

Vivian Corporation Ltd.:

Tel. +00356 22588600.

Risk Management Plan (RMP)

A risk management system, described in the risk management plan (RMP), is a set of pharmacovigilance activities and interventions required by the European Medicine Agency (EMA) to ensure that the benefits of the medicinal product outweigh its risks.

The XELJANZ RMP is developed:

- to identify, characterise, prevent or minimise risks relating to XELJANZ including the assessment of the effectiveness of those activities and interventions.

Risk Communication

In order to communicate certain risks about XELJANZ, Pfizer has worked with the EMA to develop a detailed communication plan to communicate the risks described in the summary of product characteristics, including the following items:

- patient alert card
- prescriber brochure
- prescriber treatment initiation checklist
- prescriber treatment maintenance checklist

Two treatment checklists: initiation checklist and maintenance checklists, are developed for you to be used prior to and during XELJANZ treatment. They intend to remind you of the risks associated with use of XELJANZ and the recommended tests before and during the XELJANZ treatment.

Prescriber website for Xeljanz (tofacitinib) ▼

▼ 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.

Version: 3.2 Date of approval: 03/2020

All the educational materials including patient alert card and treatment initiation/maintenance checklist are available at
www.tofacitinib-rmp.com.mt .
Please visit this website for more details.

Ongoing Risk Assessment

RA

In order to continue to characterise the risks relating to XELJANZ in treatment of RA, Pfizer has committed to to study risks within 4 established European RA registries including one in UK (i.e., BSRBR), one in Germany (i.e., RABBIT), one in Sweden (i.e., ARTIS), and one in Spain (i.e., BIOBADASER).

The purpose of the registry surveillance studies is to collect additional longitudinal safety data from the clinical practice setting regarding the use of XELJANZ in patients with rheumatoid arthritis.

Physicians from those countries can learn more about these registries via the following contact information:

- BSRBR:

  https://bsrbr.org/

- RABBIT – Rheumatoide Arthritis: Beobachtung der Biologika-Therapie:

  https://biologika-register.de

- ARTIS

  Johan.Askling@ki.se

  Clinical Epidemiology Unit and Rheumatology Unit

  Dept of Medicine

  Karolinska Institute

- BIOBADASER:

  https://biobadaser.ser.es/default.aspx

UC

In order to continue to characterize the risks relating to XELJANZ in treatment of UC, Pfizer has committed to participating in a prospective, non-interventional active surveillance study using 1 or more European UC registries, including one in Sweden (Swedish National Quality Registry for Inflammatory Bowel Disease [SWIBREG]. Another option being considered as part of this active surveillance study is United Registries for Clinical Assessment and Research (UR-CARE).

The purpose of this active study is to further understand and characterise the safety profile of tofacitinib within the clinical practice setting in patients with UC. This will include a sub-analysis of the safety profile in patients treated with XELJANZ 10 mg twice daily maintenance therapy.

Physicians from those countries can learn more about these registries via the following contact information:

- SWIBREG

  http://www.swibreg.se/

Please contact

Pfizer medical information at +30 210 6785800,

Local Representative:

Vivian Corporation Ltd., +00356 21344610.

Pfizer

XELJANZ®
(tofacitinib citrate)