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63/1

# XELJANZ®
[tofacitinib citrate]

▼ This medicinal product issubject to additional monitoring.


In the treatment of adults with
**MODERATE TO SEVERE RHEUMATOID ARTHRITIS (RA)**
who have had an inadequate response or intolerance to methotrexate[3]

# A MARK OF PROVEN EFFICACY[4-6]

**XELJANZ® – provides proven, rapid, and sustained efficacy with AND without methotrexate.[4-6]**

**An estimated 208,000 patients worldwide have been treated with XELJANZ®[7,*]**

**Up to 9.5 years of Long Term Extension study on Safety and Efficacy[6,**]**

*As of April 2019; **Efficacy data has reported up to 8 years

**ACR:** American Collage of Rheumatology; **JAK:** Janus kinase.

**References: 1.** Vyas D ve ark. Ann Pharmacother. 2013 Nov;47(11):1524-31. **2.** Paik J Deeks ED. Drugs. 2019 Apr;79(6):655-663. **3.** XELJANZ® SmPC. **4.** Fleischmann R ve ark. N Engl J Med 2012;367:495-507. **5.** Burmester GR ve ark. Lancet. 2013 Feb 9;381(9865):451-60. **6.** Wollenhaupt J ve ark. Arthritis Res Ther. 2019 Apr 5;21(1):89. **7.** Data on file.

**XELJANZ® 5 mg Film-coated Tablets**

▼ This medicinal product is subject to additional monitoring. This inverted triangle is dedicated to bringing new information related to safety. Health care providers are obligated to report suspected adverse reactions to TÜFAM.[1] **ACTIVE INGREDIENT:** Each 5 mg film-coated tablet, contains of 8.078 mg of tofacitinib citrate equivalent to 5 mg of tofacitinib free base active pharmaceutical ingredient. **INACTIVE INGREDIENT:** Each 5 mg film-coated tablet, also contains of 62.567 mg of lactose monohydrate. **CONTENT OF PACKAGE:** Foil blisters containing 56 film-coated tablets. **THERAPEUTIC INDICATIONS:** XELJANZ® is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. XELJANZ® may be used as monotherapy or in combination with methotrexate. Use of XELJANZ® in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended. XELJANZ® is indicated for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to DMARDs. **POSOLOGY/TIME AND INTERVAL OF ADMINISTRATION:** The recommended dosage is 5 mg BID for both indications. If patient develops a serious infection, the treatment should be interrupted until the infection is taken under control. Interruption of the treatment with XELJANZ® is also recommended for management of lymphopenia, neutropenia and anemia. XELJANZ® dosage should be reduced to 5 mg once daily in patients with severe renal insufficiency, with moderate hepatic impairment, receiving potent inhibitors of CYP3A4 (e.g. ketoconazole), receiving one or more concomitant medications that results in both moderate inhibition of CYP3A4 and potent inhibition of CYP2C19 (e.g. fluconazole). **METHOD OF ADMINISTRATION:** XELJANZ® is taken orally with or without food. **SPECIAL POPULATIONS: Renal failure:** No dose adjustment is required in patients with mild or moderate renal impairment. The daily dose of XELJANZ® should not exceed 5 mg in patients with severe renal impairment. In clinical trials, safety and efficacy of XELJANZ® is not evaluated in rheumatoid arthritis patients with baseline creatinine clearance values (estimated by the Cockcroft-Gault equation) less than 40 mL/min. **Hepatic failure:** No dose adjustment is required in patients with mild hepatic impairment. The daily dose should not exceed 5 mg in patients with moderate hepatic impairment. XELJANZ® should not be used in patients with severe hepatic impairment. **Pediatric population:** The safety and efficacy of XELJANZ® in children under 18 years have not yet been studied. No data is available. **Geriatric Use (≥65 years):** No dose adjustment is required in patients age ≥ 65. Limited data for patients age ≥ 75. **ADVERSE REACTIONS:** Safety profile of XELJANZ® is similar for both indications. The most commonly reported adverse reactions during the first 3 months in controlled clinical trials were headache, upper respiratory tract infections, nasopharyngitis, diarrhea, nausea and hypertension. **INFECTIONS:** The most common serious adverse reactions are serious infections. The most commonly reported severe infections with the use of XELJANZ® are pneumonia, cellulitis, herpes zoster, urinary tract infections, diverticulitis, appendicitis. Opportunistic infections have been reported with TB, and other mycobacterial infections, cryptococcal, histoplasmosis, esophageal candidiasis, multidermatomal herpes zoster, cytomegalovirus, BK virus infections and listeriosis upon the use of XELJANZ®. **LABORATORY PARAMETERS: Liver enzymes:** More than three times of the upper limit of normal (ULN) increase in liver enzymes (3xULN) is rarely observed. In patients with elevated liver enzymes, treatment modifications, such as reducing the concomitant DMARD dose, interrupting XELJANZ® therapy, or reducing the XELJANZ® dose, have resulted in a reduction or normalization of liver enzyme levels. **Lipids:** XELJANZ® treatment has been associated with increases in lipid parameters such as total cholesterol, low density lipoprotein (LDL) and high-density lipoprotein (HDL). Increases in lipid parameters (total cholesterol, LDL, HDL, triglycerides) were first assessed in the first month after the start of XELJANZ® in controlled double-blind clinical trials. Observed increases followed by stabilization. The increases in total and LDL cholesterol associated with XELJANZ® fall to pre-treatment levels with statin therapy. **INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:** Since XELJANZ® is metabolized by CYP3A4, it is likely that it interacts with the metabolism of other drugs inhibiting or inducing CYP3A4. XELJANZ®'s exposure is increased when it is co-administered with potent CYP3A4 inhibitors (e.g. ketoconazole) or when administration of one or more concomitant medications resulting in moderate inhibition of CYP3A4 and potent inhibition of CYP2C19 (e.g. fluconazole) happens. XELJANZ®'s exposure is decreased when co-administered with potent CYP3A4 inducers (e.g. rifampin). Inhibitors of CYP2C19 or P-glycoprotein are unlikely to alter the pharmacokinetics of XELJANZ®. Concomitant administration of XELJANZ® with methotrexate (15-25 mg MTX once weekly) had no effect on the pharmacokinetics of XELJANZ®. **CONTRAINDICATIONS:** XELJANZ® is contraindicated in hypersensitivity to the active substance or to any of the ingredients listed or in case of severe liver failure, pregnancy and lactation period and severe infections like active tuberculosis, sepsis or opportunistic infections. **SPECIAL WARNINGS AND PRECAUTIONS: COMBINATION WITH OTHER RA TREATMENTS:** XELJANZ® has not been studied in combination with biological DMARDs and its use should be avoided in RA patients in combination with biological DMARDs such as TNF antagonists, IL-1R antagonists, IL-6R antagonists, anti-CD20 monoclonal antibodies and selective co-stimulation modulators and potent immunosuppressants such as azathioprine and cyclosporine because of the increased risk of immunosuppression and followed by an increased risk of infection. **SERIOUS INFECTIONS:** Serious and, in some cases, fatal infections due to bacterial, mycobacterial, invasive fungal, viral or other opportunistic pathogens have been reported in patients with rheumatoid arthritis treated with XELJANZ®. The risk of opportunistic infection is higher in Asian geography. XELJANZ® should not be started with active infections, including local infections. **Tuberculosis:** Patients should be evaluated and examined for latent or active infection before and during treatment with XELJANZ® periodically. **Viral reactivation:** Before treatment with XELJANZ® is initiated, screening for viral hepatitis should be performed in accordance with clinical guidelines. **MALIGNANCY AND LYMPHOPROLIFERATIVE DISEASE:** Lymphoma and other malignancies have been observed in patients treated with XELJANZ®. The effect of XELJANZ® on the development of lymphoma and malignancy is unknown. Non-melanoma skin cancers (NMSC) have been reported in patients treated with XELJANZ®. Periodic skin examination is recommended for patients who are at increased risk for skin cancer. **GASTROINTESTINAL PERFORATIONS:** Events of gastrointestinal perforation have been reported in clinical studies with XELJANZ® in rheumatoid arthritis patients, although the role of JAK inhibition in these events is not known. XELJANZ® should be used with caution in patients who are at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis). Patients presenting with new onset abdominal symptoms should be evaluated promptly for early identification of gastrointestinal perforation. **LABORATORY PARAMETERS: Lymphocytes:** XELJANZ® treatment has been associated with an increased incidence of lymphopenia compared with placebo. Lymphocyte counts below 750 cells/mm$^3$ were associated with an increased incidence of severe infection. XELJANZ® therapy should not be initiated or continued in patients who are confirmed to have a lymphocyte lower than 750 cells/mm$^3$. The lymphocytes level should be observed at beginning of treatment; after 4-8 weeks and then every three months. **Neutrophils:** XELJANZ® treatment has been associated with an increased incidence of neutropenia (<2000 cells/mm$^3$) when compared to placebo. It is not recommended to start XELJANZ® treatment in patients with ANC less than 1000 cells/mm$^3$. Neutrophil counts should be monitored at the beginning of treatment, after 4-8 weeks, and every 3 months thereafter. **Hemoglobin:** XELJANZ® treatment has been associated with a decrease in hemoglobin level. It is not recommended to start XELJANZ® treatment in patients with a hemoglobin level below 9 g/dL. The level of hemoglobin should be monitored at the beginning of treatment, 4-8 weeks after treatment and then every three months thereafter. **VACCINATION:** It is recommended that all patients vaccinations should be completed in accordance with current immunization guidelines before starting XELJANZ® treatment. Administration of live vaccines with XELJANZ® is not recommended. **OVERDOSE AND MANAGEMENT OF OVERDOSE:** There are currently no specific antidotes for treating overdose with XELJANZ®. Treatment should be symptomatic and supportive. **PREGNANCY AND LACTATION:** Pregnancy category is C. **Pregnancy period:** There is not enough data on the use of tofacitinib in pregnant women. Studies in rats and rabbits have shown that tofacitinib is teratogenic and also affects delivery and peri/ postnatal development. As a precautionary measure, the use of XELJANZ® is contraindicated in pregnancies. **Lactation period:** It is not known whether tofacitinib is excreted in human milk. But the risk of being harmful to the breastfeeding baby cannot be ignored. Tofacitinib has been passed on to suckling rats. As a precautionary measure, the use of XELJANZ® is contraindicated during the lactation period. **ABILITY TO DRIVE OR OPERATE MACHINERY:** Tofacitinib has no or negligible effect on the ability to drive a vehicle or operate machinery. **STORAGE:** Store XELJANZ® at room temperature, below 30°C and inside the original package. **SHELF-LIFE:** 24 months. **MARKETING AUTHORIZATION HOLDER:** Pfizer İlaçları Ltd. Şti. Muallim Naci Cad. No:55 34347 Ortaköy/İstanbul. **AUTHORIZATION DATE AND NUMBER:** First authorization date: 07/05/2015 2015/335. Sold by prescription. Currently reimbursed by Social Security Institution. For further information, please contact us. **VAT INCLUDED RETAIL PRICE AND APPROVAL DATE:** XELJANZ® 5 mg film-coated tablet: 2.917,84 TL (19.02.2020). **SmPC APPROVAL DATE:** 06.08.2019.

[1] Türkiye Farmakovijilans Merkezi: Turkish Pharmacovigilance Center.

TOF 2020 (March 2020)

Pfizer Inflammation & Immunology

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Gülhane Medical Journal is the official scientific publication of the Gülhane Faculty of Medicine, University of Health Sciences Turkey.



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Gülhane Medical Journal (Gulhane Med J) is the official, scientific, peer-reviewed, international journal of Gülhane Faculty of Medicine, University of Health Sciences Turkey. The journal accepts submissions on all aspects of general medicine. Featured article types include original articles, case reports, reviews, and letters to the editor. The history of the Gülhane Medical Journal dates back to 1871 and it was named with its current title in 1999.

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Gülhane Medical Journal (GMJ) is an international, multidisciplinary and peer reviewed journal for researchers and health-care providers. It is published four times a year, and accepts submissions in English. It is the official journal of the Gülhane Faculty of Medicine, University of Health Sciences Turkey.

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The authors must declare that their submitted article has neither been published in any journal, nor been simultaneously submitted to another journal. Presentations as an abstract at a scientific meeting is an exception but this should be declared in the cover letter.

The Methods section should include a statement indicating that the research was approved by an independent local, regional or national review body (e.g., ethics committee, institutional review board). If the study includes human subjects, the author should declare openly that the work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans (link- https://www.wma.net/policies-post/wma-international-code-of-medical-ethics/), and Uniform Requirements for manuscripts submitted to Biomedical journals (link- http://www.icmje.org/). The name of the institution and the code of approval (i.e., approval number) must be provided. Authors should include a statement in the manuscript about informed consent obtained from their participants. According to the most recent regulations by the Turkish Academic Network and Information Center (ULAKBIM), the authors (s) of a case report must include a statement in their manuscript that written, informed consent was obtained from the patient.

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Importantly, the title page must be uploaded separately, no page breaks should be used and all pages should be numbered (below, centered) consecutively.

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It should be structured according to Aims, Methods, Results, Conclusions

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