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ספטמבר 2026

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיע על עדכונים בעלונים לרופא של התכשירים Xeljanz 5 mg, Xeljanz 10 mg, Xeljanz XR 11 mg ו- Xeljanz 1 mg/ml. הודעה זו מפרטת את העדכונים המהווים החמרה במידע הבטיחות בלבד, למידע מלא יש לעיין בעלונים. העלונים מפורסמים במאגר התרופות שבמשרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום:
חברת פיזר פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133, הרצליה

שם התכשירים:

Xeljanz 5mg
Xeljanz 10 mg
Xeljanz XR 11 mg
Xelbanz 1 mg/ml

הרכב וחוזק:

Xeljanz 5, 10 mg: Each tablet contains tofacitinib citrate, equivalent to 5/10 mg tofacitinib
Xeljanz XR 11 mg: Each extended-release tablet contains tofacitinib citrate, equivalent to 11 mg tofacitinib
Xeljanz 1 mg/ml: Each mL oral solution contains tofacitinib citrate, equivalent to 1 mg tofacitinib.

התוויות מאושרות:

Rheumatoid arthritis

Tofacitinib 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 (DMARDs). Tofacitinib can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate.

Psoriatic arthritis

Tofacitinib 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 antirheumatic drug (DMARD) therapy.

Ankylosing spondylitis

Tofacitinib is indicated for the treatment of adult patients with active ankylosing spondylitis (AS) who have responded inadequately to conventional therapy.

Ulcerative colitis

Tofacitinib 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.

Juvenile idiopathic arthritis (JIA)

Tofacitinib is indicated for the treatment of active polyarticular juvenile idiopathic arthritis (rheumatoid factor positive [RF+] or negative [RF-] polyarthritis and extended oligoarthritis), and juvenile psoriatic arthritis (PsA) in patients 2 years of age and older, who have responded inadequately to previous therapy with disease modifying antirheumatic drugs DMARDs.

Tofacitinib can be given in combination with methotrexate (MTX) or as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

להלן עדכוני הבטיחות בעלונים לרופא (מסומנים בצהוב):

4.4 Special warnings and precautions for use

Viral reactivation

Viral reactivation and cases of herpes virus reactivation (e.g., herpes zoster) have been observed in patients receiving tofacitinib (see section 4.8)..

In patients treated with tofacitinib, the incidence of herpes zoster appears to be increased in:

- Japanese or Korean patients.
- Patients with an ALC less than 1,000 cells/mm³ (see section 4.2).
- Patients with long standing RA who have previously received two or more biological disease modifying antirheumatic drugs (DMARDs).
- Patients treated with 10 mg twice daily.

The impact of tofacitinib on chronic viral hepatitis reactivation is unknown. Patients screened positive for hepatitis B or C were excluded from clinical studies. Screening for viral hepatitis should be performed in accordance with clinical guidelines before starting therapy with tofacitinib.

Progressive multifocal leukoencephalopathy (PML) has been reported during post marketing use of tofacitinib for the treatment of autoimmune diseases (including off-label use). PML can be fatal and should be considered in the differential diagnosis in immunosuppressed patients with new onset or worsening neurological symptoms. If PML is suspected, withhold dosing with tofacitinib during appropriate diagnostic evaluation. If PML is confirmed, treatment with tofacitinib should be discontinued.