פייזר פרמצבטיקה ישראל בע"מ
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הרצליה פיתוח, ישראל
טל: 972-9-9700500 פקס: 972-9-9700501

אוקטובר 2024

רופא/ה, רוקח/ת נכבד/ה,

חברת פייזר, מבקשת להודיעכם על על עדכון בעלון לרופא של התכשיר ליטפולו 50 מ"ג.
הודעה זו מפרטת את העדכונים המהווים החמרה במידע הבטיחותי בלבד, למידע מלא יש לעיין בעלון.
העלונים לרופא ולצרכן מפורסמים במאגר התרופות שבמשרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום:
חברת פייזר פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133, הרצליה פיתוח.

שם התכשיר: ליטפולו 50 מ"ג, Litfulo 50 mg

הרכב וחוזק:

Each hard capsule contains ritlecitinib tosylate equivalent to 50 mg ritlecitinib

התוויה מאושרת:

LITFULO is a kinase inhibitor indicated for the treatment of severe alopecia areata in adults and adolescents 12 years and older.
Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants

להלן עדכוני הבטיחות בעלון לרופא (מסומנים בצהוב):

4.4 Special warnings and precautions for use

Malignancy (including non-melanoma skin cancer)

Malignancies, including non-melanoma skin cancer (NMSC) have been reported in patients receiving ritlecitinib.

It is not known whether selective JAK3 inhibition may be associated with adverse reactions of Janus Kinase (JAK) inhibition predominantly involving JAK1 and JAK2. In a large randomised active-controlled study of tofacitinib (another JAK inhibitor) in rheumatoid arthritis (RA) patients 50 years and older with at least one additional cardiovascular risk factor, a higher rate of malignancies, particularly lung cancer, lymphoma and NMSC, was observed with tofacitinib compared to tumour necrosis factor (TNF) inhibitors. In this study, current or past long-time smokers and patients 65 years of age and older had an additional increased risk of overall malignancies.

Limited clinical data are available to assess the potential relationship of exposure to ritlecitinib and the development of malignancies. Long-term safety evaluations are ongoing. The risks and benefits of ritlecitinib treatment should be considered prior to initiating or continuing therapy in patients with a known malignancy other than a successfully treated NMSC or cervical cancer.

Periodic skin examination is recommended for patients who are at increased risk of skin cancer.

Major adverse cardiovascular events (MACE), deep venous thrombosis (DVT) and pulmonary embolism (PE)

Events of venous and arterial thromboembolism, including MACE, have been reported in patients receiving ritlecitinib.

It is not known whether selective JAK3 inhibition may be associated with adverse reactions of JAK inhibition predominantly involving JAK1 and JAK2. In a large randomised active-controlled study of tofacitinib (another JAK inhibitor) in RA patients 50 years and older with at least one additional cardiovascular risk factor, a higher rate of MACE, defined as cardiovascular death, non-fatal myocardial infarction and non-fatal stroke, and a dose -dependent higher rate of venous thromboembolism including DVT and PE were observed with tofacitinib compared to TNF inhibitors. In this study, current or past long-time smokers and patients 65 years of age and older had an additional increased risk for major adverse cardiovascular events (MACE).

Long-term safety evaluations for ritlecitinib are ongoing. Ritlecitinib should be used with caution in patients with known risk factors for thromboembolism. In patients with a suspected thromboembolic event, discontinuation of ritlecitinib and prompt re-evaluation is recommended. The risks and benefits of ritlecitinib treatment should be considered prior to initiating therapy in patients.