

10/2024

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

הנדון: Stelara® Pre-filled pen
סטלרה™ עט מוכן לשימוש

חברת J-C Health Care Ltd מבקשת להודיעכם כי העלון לרופא של התכשיר שבנדון התעדכנו ב 10.2024.
פרטי העדכון העיקריים מופיעים בהמשך (טקסט שהושמט מסומן בטקסט **בחול עם קו חוצה**, טקסט המהווה החמרה מודגש **ברקע צהוב**).

ההתוויות העדכניות המאושרות לתכשיר בישראל:

Plaque psoriasis

STELARA is indicated for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate or PUVA (psoralen and ultraviolet A).

Psoriatic arthritis (PsA)

STELARA, alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease modifying anti rheumatic drug (DMARD) therapy has been inadequate.

Crohn's Disease

STELARA is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF α antagonist or have medical contraindications to such therapies.

Ulcerative colitis

STELARA is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.

מרכיב פעיל: Ustekinumab 90mg/ml

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
<https://israel.drugs.health.gov.il/#!/byDrug>

כמו כן, מצורפים לפרסום זה וניתן לקבל העתק מודפס שלהם באמצעות פנייה לבעל הרישום: J-C Health Care Ltd, קיבוץ שפיים, 6099000, טל': 09-9591111.

בברכה,

שרון כץ
רוקחת ממונה
J-C Health Care Ltd

העדכון בעלון לרופא הינו:

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4.4 Special warnings and precautions for use

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Malignancies

Immunosuppressants like ustekinumab have the potential to increase the risk of malignancy. Some patients who received STELARA in clinical studies and in a post-marketing observational study in patients with psoriasis developed cutaneous and non-cutaneous malignancies (see section 4.8). The risk of malignancy may be higher in psoriasis patients who have been treated with other biologics during the course of their disease.

No studies have been conducted that include patients with a history of malignancy or that continue treatment in patients who develop malignancy while receiving STELARA. Thus, caution should be exercised when considering the use of STELARA in these patients.

All patients, in particular those greater than 60 years of age, patients with a medical history of prolonged immunosuppressant therapy or those with a history of PUVA treatment, should be monitored for the appearance of **non-melanoma** skin cancer (see section 4.8).