

09/2026

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

הנדון: Stelara 130mg

חברת J-C Health Care Ltd מבקשת להודיעכם כי העלון לרופא של התכשיר שבנדון התעדכן ב 09.2026.
פרטי העדכון העיקריים מופיעים בהמשך (קו תחת משמעו תוספת טקסט, החמרות מסומנות בצהוב, טקסט שנמחק מסומן בקו חוצה). העלונים מכילים גם שינויים עריכתיים.

ההתוויות המאושרות לתכשיר בישראל:

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

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.

מומלץ לקרוא בעיון את כל תוכן העלונים ולעדכן את המטופלים במידע הרלוונטי להם.

בברכה,

סיון דוד
רוקחת ממונה
J-C Health Care Ltd

העדכונים העיקריים בעלון לרופא:

4.8 Undesirable effects

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Hypersensitivity and infusion reactions

In Crohn's disease and ulcerative colitis intravenous induction studies, no events of anaphylaxis or other serious infusion reactions were reported following the single intravenous dose. In these studies, 2.2% of 785 placebo-treated patients and 1.9% of 790 patients treated with the recommended dose of ustekinumab reported adverse events occurring during or within an hour of the infusion. Serious infusion-related reactions including anaphylactic reactions to the infusion have been reported in the post-marketing setting (see section 4.4). **In the post-marketing setting, some cases of serious hypersensitivity reactions have been reported in patients with a history of alpha-gal syndrome, allergy to mammalian meat or meat products, or anti-alpha-gal IgE. In most of these cases the reactions occurred at the time of initial administration.**

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Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form <https://sideeffects.health.gov.il/> – <https://reportsideffect.health.gov.il/drugs/home>