J-C Health Care Ltd.

Kibbutz Shefayim 6099000, ISRAEL
tel +972-9-959-1111
fax +972-9-958-3636

07/2023

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 07/2023.

פרטי העדכון העיקריים מופיעים בהמשך (טקסט שנוסף מסומן באדום, טקסט שהושמט מסומן בטקסט ~~בחול עם קו חוצה~~, טקסט המהווה החמרה מודגש ברקע צהוב ),אך קיימים עדכונים נוספים.

**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 TNFα 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://israeldrugs.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,

יעל לפידות מללי
רוקחת ממונה
J-C Health Care Ltd

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**העדכון בעלון לרופא הינו:**

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Mechanism of action

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In patients with ulcerative colitis, treatment with ustekinumab resulted in a decrease in inflammatory markers including CRP and fecal calprotectin during the induction phase, which was maintained throughout the maintenance phase and study extension through week ~~92~~200.

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Crohn's Disease

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In IM-UNITI, patients who completed the study through week 44 were eligible to continue treatment in a study extension. Among the ~~718~~ 567 patients who entered on and were treated with ustekinumab in the study extension, clinical remission and response were generally maintained through week 252 for both patients who failed TNF-therapies and those who failed conventional therapies.

No new safety concerns were identified in this study extension with up to 5 years of treatment in patients with Crohn's Disease.

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Ulcerative colitis

*Study Extension*

In UNIFI, patients who completed the study through week 44 were eligible to continue treatment in a study extension. Among the ~~588~~ 400 patients who entered on and were treated with ustekinumab every 12 or 8 weeks in the study extension, symptomatic remission was generally maintained through week ~~92~~ 200 for patients who failed conventional therapy (but not a biologic therapy) and those who failed biologic therapy, including those who failed both anti-TNF and vedolizumab. Among patients who received 4 years of ustekinumab treatment and were assessed using the full Mayo score at maintenance week 200, 74.2% (69/93) and 68.3% (41/60) maintained mucosal healing and clinical remission, respectively.

No new safety concerns were identified in this study extension with up to ~~2~~4 years of treatment in patients with ulcerative colitis.

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*Health-related quality of life*

Health-related quality of life was assessed by Inflammatory Bowel Disease Questionnaire (IBDQ), SF-36 and EuroQoL-5D (EQ-5D) questionnaires.

At week 8 of UNIFI-I, patients receiving ustekinumab showed significantly greater and clinically meaningful improvements on IBDQ total score, EQ-5D and EQ-5D VAS, and SF-36 Mental Component Summary Score and SF-36 Physical Component Summary Score when compared to placebo. These improvements were maintained in ustekinumab-treated patients in UNIFI-M through week 44. Improvement in health-related quality of life as measured by IBDQ and SF-36 was generally maintained during the extension through week ~~92~~200.