

J-C Health Care Ltd.

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04/2023

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 04/2023.
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 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

Ustekinumab מרכיב פעיל:

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,

יעל לפידות מללי
רוקחת ממונה
J-C Health Care Ltd

4.4 Special warnings and precautions for use

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Infections

Ustekinumab may have the potential to increase the risk of infections and reactivate latent infections. In clinical studies **and a post-marketing observational study in patients with psoriasis**, serious bacterial, fungal, and viral infections have been observed in patients receiving STELARA (see section 4.8).

Opportunistic infections including reactivation of tuberculosis, other opportunistic bacterial infections (including atypical mycobacterial infection, listeria meningitis, pneumonia legionella, and nocardiosis), opportunistic fungal infections, opportunistic viral infections (including encephalitis caused by herpes simplex 2), and parasitic infections (including ocular toxoplasmosis) have been reported in patients treated with ustekinumab.

Caution should be exercised when considering the use of STELARA in patients with a chronic infection or a history of recurrent infection (see section 4.3).

Prior to initiating treatment with STELARA, patients should be evaluated for tuberculosis infection. STELARA must not be given to patients with active tuberculosis (see section 4.3). Treatment of latent tuberculosis infection should be initiated prior to administering STELARA. Anti-tuberculosis therapy should also be considered prior to initiation of STELARA in patients with a history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. Patients receiving STELARA should be monitored closely for signs and symptoms of active tuberculosis during and after treatment.

Patients should be instructed to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, the patient should be closely monitored and STELARA should not be administered until the infection resolves.

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).

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Cardiovascular events

Cardiovascular events including myocardial infarction and cerebrovascular accident have been

observed in patients with psoriasis exposed to STELARA in a post-marketing observational study. Risk factors for cardiovascular disease should be regularly assessed during treatment with STELARA.

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4.8 Undesirable effects

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Paediatric population

~~Undesirable effects in p~~*Paediatric patients* ~~12~~ 6 years and older with plaque psoriasis.

The safety of ustekinumab has been studied in two phase 3 studies of paediatric patients with moderate to severe plaque psoriasis. a phase 3 ~~The first study of~~ was in 110 patients from 12 to 17 years of age treated for up to 60 weeks and the second study was in 44 patients from 6 to 11 years of age treated for up to 56 weeks. In general this study, the adverse events reported in these two studies with safety data up to 1 year were similar to those seen in previous studies in adults with plaque psoriasis.