J-C Health Care Ltd.
Kibbutz Shefayim 6099000, ISRAEL
tel +972-9-959-1111
fax +972-9-958-3636

Johnson&Johnson

03/2025

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

הנדון: Stelara 45mg vial; Stelara Prefilled syringe

חברת J-C Health Care Ltd מבקשת להודיעכם כי העלון לרופא והעלון לצרכן של התכשירים שבנדון התעדכנו ב 03.2025.

ההתוויות העדכניות המאושרות לתכשיר בישראל:

Plaque psoriasis
STELARA is indicated for the treatment of moderate to severe plaque psoriasis in adult patients (18 years or older) who have failed to, have a contraindication to, or who are intolerant to other systemic therapies including ciclosporin, methotrexate or Psoralen plus U.V (PUVA).

Paediatric plaque psoriasis
STELARA is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescent patients from the age of 6 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

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 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

פרטי העדכון העיקריים מופיעים בהמשך (טקסט שנוסף מסומן בקו תחתון, טקסט שהושמט מסומן בטקסט ~~בחול עם קו חוצה~~, טקסט המהווה החמרה מודגש ברקע צהוב).

העלונים לרופא ולצרכן מכילים גם שינויי עריכה.

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

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,

סיון דוד
רוקחת ממונה
J-C Health Care Ltd

J-C Health Care Ltd.
Kibbutz Shefayim 6099000, ISRAEL
tel +972-9-959-1111
fax +972-9-958-3636

Johnson&Johnson

העדכונים העיקריים בעלון לרופא:

…

4.4 Special warnings and precautions for use

…

Polysorbate 80
STELARA contains 0.04 mg (90 mg/1.0mL) or 0.02 mg (45 mg/0.5 mL) of polysorbate 80 (E433) in each dosage unit which is equivalent to 0.04 mg/mL. Polysorbates may cause allergic reactions.

…

4.5 Interaction with other medicinal products and other forms of interaction

…
~~No interaction studies have been performed in humans.~~ In the population pharmacokinetic analyses of the phase-3 studies, the effect of the most frequently used concomitant medicinal products in patients with psoriasis (including paracetamol, ibuprofen, acetylsalicylic acid, metformin, atorvastatin, levothyroxine) on pharmacokinetics of ustekinumab was explored

…
The results of an *in vitro* study and a phase 1 study in subjects with active Crohn's disease do not suggest the need for dose adjustments in patients who are receiving concomitant CYP450 substrates (see section 5.2).

4.8 Undesirable effects

…
Tabulated list of adverse reactions
The safety data described below reflect exposure in adults to ustekinumab in 14 phase 2 and phase 3 studies in 6,7100~~9~~ patients (4,135 with psoriasis and/or psoriatic arthritis, 1,749 with Crohn's disease and 826~~5~~ patients with ulcerative colitis). This includes exposure to STELARA in the controlled and non-controlled periods of the clinical studies in patients with psoriasis, psoriatic arthritis, Crohn's disease or ulcerative colitis for at least 6 months ~~or 1 year~~ (4,577 patients)~~and~~ or at least 1 year (3,648~~253~~ patients). ~~respectively with psoriasis, psoriatic arthritis, Crohn's disease or ulcerative colitis) and exposure for at least 4 or 5 years (~~2,194~~1,482~~ patients with psoriasis, Crohn's disease or ulcerative colitis for at least 4 years while 1,148 ~~and 838~~ patients with psoriasis or Crohn's disease ~~respectively).~~ were exposed for at least 5 years.
….

In the controlled and non-controlled periods of psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis clinical studies, representing 15,227~~11,581~~ patient-years of ustekinumab exposure in 6,7100~~9~~ patients, the median follow-up was 1.~~0~~2 years; 1.~~1~~ 7 years for psoriatic disease studies, 0.6 year for Crohn's disease studies, and ~~1.0~~2.3 years for ulcerative colitis studies. The rate of infection was 0.85~~91~~ per patient-year of follow-up in ustekinumab-treated patients, and the rate of serious infections was 0.02 per patient-year of follow-up in ustekinumab-treated patients (289~~199~~ serious infections in 15,227~~11,581~~ patient-years of follow-up) and serious infections reported included pneumonia, anal abscess, cellulitis, diverticulitis, gastroenteritis and viral infections.
…

Malignancies
…
In the controlled and non-controlled periods of psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis clinical studies, representing 15,205~~11,561~~ patient-years of ustekinumab exposure in 6,7100~~9~~ patients, the median follow-up was 1.2~~0~~ years; 1.7~~1~~ years for psoriatic disease studies, 0.6 year

J-C Health Care Ltd.
Kibbutz Shefayim 6099000, ISRAEL
tel +972-9-959-1111
fax +972-9-958-3636

Johnson&Johnson

for Crohn's disease studies and ~~1.0~~2.3 years for ulcerative colitis studies. Malignancies excluding non-melanoma skin cancers were reported in 76~~62~~ patients in 15,205~~11,561~~ patient-years of follow-up (incidence of 0.50~~4~~ per 100 patient-years of follow-up for ustekinumab-treated patients). The incidence of malignancies reported in ustekinumab-treated patients was comparable to the incidence expected in the general population (standardised incidence ratio = 0.94~~3~~ [95% confidence interval: 0.73~~1~~, 1.~~20~~18], adjusted for age, gender and race). The most frequently observed malignancies, other than non-melanoma skin cancer, were prostate, melanoma, colorectal, ~~melanoma~~ and breast cancers. The incidence of non-melanoma skin cancer was 0.46~~9~~ per 100 patient-years of follow-up for ustekinumab-treated patients (69~~56~~ patients in 15,165~~11,545~~ patient-years of follow-up). The ratio of patients with basal versus squamous cell skin cancers (3:1) is comparable with the ratio expected in the general population (see section 4.4).
…

5.1 Pharmacodynamic properties

…

Study Extension

In UNIFI, patients who completed the study through week 44 were eligible to continue treatment in a study extension. Among the 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 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.
The safety analysis including 457 patients (1289.9 person-years) followed up to 220 weeks showed a safety profile between week 44 and 220 that was comparable with that observed up to week 44.

…

5.2 Pharmacokinetic properties

…

Regulation of CYP450 enzymes

The effects of IL-12 or IL-23 on the regulation of CYP450 enzymes were evaluated in an *in vitro* study using human hepatocytes, which showed that IL-12 and/or IL-23 at levels of 10 ng/mL did not alter human CYP450 enzyme activities (CYP1A2, 2B6, 2C9, 2C19, 2D6, or 3A4; see section 4.5).

A phase 1, open-label, drug interaction study, Study CNTO1275CRD1003, was conducted to evaluate the effect of ustekinumab on cytochrome P450 enzyme activities following induction and maintenance dosing in patients with active Crohn's disease (n=18). No clinically significant changes in exposure of caffeine (CYP1A2 substrate), warfarin (CYP2C9 substrate), omeprazole (CYP2C19 substrate), dextromethorphan (CYP2D6 substrate), or midazolam (CYP3A substrate) were observed when used concomitantly with ustekinumab at the approved recommended dosing in patients with Crohn's disease (see section 4.5).

העדכונים העיקריים בעלון לצרכן:

2.לפני השימוש בתרופה

....

מידע חשוב על חלק מהמרכיבים של התרופה
סטלרה מכילה פוליסורבט 80 (polysorbate 80)
סטלרה מכילה 0.02 מ"ג פוליסורבט 80 (E433) בכל יחידת מינון שוות ערך ל0.04מ"ג/מ"ל. פוליסורבט עלול לגרום לתגובה אלרגית. ספר לרופא אם יש לך אלרגיות ידועות.