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

Johnson&Johnson

10/2024

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 10.2024.

פרטי העדכון העיקריים מופיעים בהמשך (טקסט שהושמט מסומן כטקסט ~~כחול עם קו חוצה~~, טקסט המהווה החמרה מודגש ברקע צהוב).

ההתוויות העדכניות 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,

שרון כץ
רוקחת ממונה
J-C Health Care Ltd

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העדכונים העיקריים בעלון לרופא:

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4.4 Special warnings and precautions for use

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Vaccinations
It is recommended that live viral or live bacterial vaccines (such as Bacillus of Calmette and Guérin (BCG)) should not be given concurrently with STELARA. Specific studies have not been conducted in patients who had recently received live viral or live bacterial vaccines. No data are available on the secondary transmission of infection by live vaccines in patients receiving STELARA. Before live viral or live bacterial vaccination, treatment with STELARA should be withheld for at least 15 weeks after the last dose and can be resumed at least 2 weeks after vaccination. Prescribers should consult the Summary of Product Characteristics for the specific vaccine for additional information and guidance on concomitant use of immunosuppressive agents post vaccination.

Administration of live vaccines (such as the BCG vaccine) to infants exposed in utero to ustekinumab is not recommended for ~~six~~ twelve months following birth or until ustekinumab infant serum levels are undetectable (see sections 4.5 and 4.6). If there is a clear clinical benefit for the individual infant, administration of a live vaccine might be considered at an earlier timepoint, if infant ustekinumab serum levels are undetectable.

Patients receiving STELARA may receive concurrent inactivated or non live vaccinations.

Long term treatment with STELARA does not suppress the humoral immune response to pneumococcal polysaccharide or tetanus vaccines (see section 5.1).

4.5 Interaction with other medicinal products and other forms of interaction

Live vaccines should not be given concurrently with STELARA.

Administration of live vaccines (such as the BCG vaccine) to infants exposed in utero to ustekinumab is not recommended for ~~six~~ twelve months following birth or until ustekinumab infant serum levels are undetectable (see sections 4.4 and 4.6). If there is a clear clinical benefit for the individual infant, administration of a live vaccine might be considered at an earlier timepoint, if infant ustekinumab serum levels are undetectable.

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4.6 Fertility, pregnancy and lactation

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Pregnancy
Data from a moderate number of prospectively collected pregnancies following exposure to STELARA with known outcomes, including more than 450 pregnancies exposed during the first trimester, do not indicate an increased risk of major congenital malformations in the newborn .

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonic/foetal development, parturition or postnatal development (see section 5.3).

However, the available clinical experience is limited. As a precautionary measure, it is preferable to avoid the use of STELARA in pregnancy.

Ustekinumab crosses the placenta and has been detected in the serum of infants born to female patients treated with ustekinumab during pregnancy. The clinical impact of this is unknown, however, the risk of

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infection in infants exposed in utero to ustekinumab may be increased after birth. Administration of live vaccines (such as the BCG vaccine) to infants exposed in utero to ustekinumab is not recommended for ~~6~~ twelve months following birth or until ustekinumab infant serum levels are undetectable (see sections 4.4 and 4.5). If there is a clear clinical benefit for the individual infant, administration of a live vaccine might be considered at an earlier timepoint, if infant ustekinumab serum levels are undetectable.