EACH LIFE IS UNIQUE

יוני 2025

רופא/ה, רוקח/ת נכבד/ה,

חב' קמהדע מודיעה על עדכון עלון התכשיר הביוסימילארי:

<u>Ustekinumab Kamada Pre-filled Syringe; אוסטקינומאב קמהדע מזרק מוכן לשימוש</u>

מרכיבים פעילים: Ustekinumab 90 mg/ml
צורת מינון ודרך מתן: Solution for subcutaneous (SC) injection

התוויות רשומות:

Plaque psoriasis
Ustekinumab Kamada 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 (MTX) or Psoralen plus UV (PUVA).
Paediatric plaque psoriasis
Ustekinumab Kamada is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescent patients from the age of 6 years and older (weighing at least 60 kg), who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.
Psoriatic arthritis (PsA)
Ustekinumab Kamada, 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
Ustekinumab Kamada 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.

עדכוני עלון: הסרת התוויה של UC, עדכונים והחמרות. טקסט המהווה החמרה מסומן בצהוב, טקסט שנוסף מסומן בכחול; בעלונים ישנם שינויים נוספים אשר אינם מהווים החמרות.

<u>עלון לרופא:</u>

4.4 Special warnings and precautions for use
…Polysorbate 80
Ustekinumab Kamada contains 0.02 mg (45 mg/0.5 mL) or 0.04 mg (90 mg/1.0 mL) of polysorbate 80 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).
...

HEAD OFFICE
2 Holzman St., Science Park, P.O. Box 4081, Rehovot, Israel, 7670402
Tel: +972.8.9406472 | Fax: +972.8.9406473 | www.kamada.com

MANUFACTURING PLANT
Kibbutz Beit Kama, M.P. Negev, Israel, 8532500
Tel: +972.8.9913111 | Fax: +972.8.9912083

kamada
EACH LIFE IS UNIQUE

4.8 Undesirable effects

Number of patients exposed in clinical studies was updated.

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).

עלון לצרכן:

2. לפני השימוש בתרופה

...

מידע חשוב על חלק מהמרכיבים של התרופה

אוסטקינומאב קמהדע מכילה פוליסורבט 80 (polysorbate 80) בכמות של 0.04 מ"ג ב-1 מ"ל. פוליסורבט עלול לגרום לתגובה אלרגית.
ספר לרופא אם יש לך אלרגיות ידועות.

העלון לרופא והעלון לצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים ע"י פניה לבעל הרישום, חברת קמהדע בע"מ (טל' 08-9406472). להלן הקישור למאגר התרופות:
https://israeldrugs.health.gov.il/#!/byDrug

HEAD OFFICE
2 Holzman St., Science Park, P.O. Box 4081, Rehovot, Israel, 7670402
Tel: +972.8.9406472 | Fax: +972.8.9406473 | www.kamada.com

MANUFACTURING PLANT
Kibbutz Beit Kama, M.P. Negev, Israel, 8532500
Tel: +972.8.9913111 | Fax: +972.8.9912083