

May 2025

Wezlana pre-filled syringe, (ustekinumab 90 mg/mL and 45mg/0.5 mL) solution for injection
Wezlana 45 mg vial, (ustekinumab 90 mg/mL) solution for injection

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

אמג'ן אירופה בי.וי, בעלת הרישום, מבקשת להודיעך על עדכונים בעלון לרופא ולצרכן של התכשיר **Wezlana**. בהודעה זו מפורטים השינויים המשמעותיים. קו תחתי מציין תוספת טקסט, קו חוצה מציין מחיקה.

ההתוויות המאושרות:

Plaque psoriasis

WEZLANA is indicated for the treatment of moderate to severe plaque psoriasis in adult patients (18 years or older) who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or PUVA (psoralen and ultraviolet A).

Pediatric plaque psoriasis

WEZLANA 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)

WEZLANA, 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

WEZLANA 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

WEZLANA 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.

העדכונים העיקריים בעלון לרופא:

4.4 Special warnings and precautions for use

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Polysorbate 80

WEZLANA 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

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~~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

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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).

5.1 Pharmacodynamic properties

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Study Extension

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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

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Regulation of CYP450 enzymes

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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

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מידע חשוב על חלק מהמרכיבים של התרופה

וזלנה מכילה פוליסורבט 80 (polysorbate 80).

וזלנה 90 מ"ג מכילה 0.04 מ"ג וזלנה 45 מ"ג מכילה 0.02 מ"ג פוליסורבט 80 (E 433) בכל יחידת מינון, שהן שוות ערך ל 0.04 מ"ג/מ"ל. פוליסורבט עלול לגרום לתגובה אלרגית. ספר לרופא אם יש לך אלרגיות ידועות.

העלונים לרופא ולצרכן נשלחו לפרסום במאגר התרופות של אתר משרד הבריאות, וניתן לקבלם גם על-ידי פניה למפיץ המקומי של התרופה, חברת מדיסון פארמה. שרות לקוחות: Medison-CS@medison.co.il טלפון: *5634

בברכה,
חברת אמג'ן