ינואר 2026

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

<u>חברת תרו אינטרנשיונל בע"מ מבקשת להודיע על עדכונים בעלון לצרכן של התכשיר שבנדון:</u>

Ilumya אילומיה

<u>התוויה מאושרת:</u>

Treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

<u>מרכיבים פעילים:</u>

Tildrakizumab 100 mg/ml

צורת המתן של התכשיר: תמיסה להזרקה

שינויים בעלונים המהווים החמרה מודגשים ברקע צהוב, תוספות מסומנות בצבע אדום והשמטות מסומנות בקו אופקי. כמו כן, בעלונים בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה.

העלון מפורסם במאגר התרופות שבאתר משרד הבריאות: https://israeldrugs.health.gov.il, ניתן לקבלו מודפס על ידי פנייה לבעל הרישום: חברת תרו אינטרנשיונל בע"מ, רחוב הקיטור 14 . מפרץ חיפה 2624761 , טל. 04-8475700

<u>להלן העדכונים העיקריים בעלון לצרכן:</u>

היריון והנקה

אם את בהיריון או מיניקה, חושבת שאת בהיריון או מתכננת להרות, יש להיוועץ ברופא לפני השימוש בתרופה זו.

<u>היריון</u>

אילומיה עוברת את השליה ועשויה להימצא אצל תינוקות שנחשפו לתרופה במהלך ההיריון. הרופא ישקול את ההשפעה הקלינית האפשרית של אילומיה אצל תינוקות שנחשפו לתרופה ברחם. ~~לא ידוע אם תרופה זו יכולה להזיק לעובר.~~

<u>להלן העדכונים העיקריים בעלון לרופא:</u>

8.1 Clinical Trials Experience

[…]

Table 1: Adverse Reactions Occurring in ≥ 1% of Subjects in the ILUMYA Group and More Frequently than in the Placebo Group in the Plaque Psoriasis Trials 1, 2, and 3

Adverse Reaction	ILUMYA 100 mg (N=705) N (%)	Placebo (N=355) N (%)
Upper respiratory infections*	98 (14)	41 (12)
Injection site reactions†	24 (3)	7 (2)
Diarrhea	13 (2)	5 (1)

* Upper respiratory infections include nasopharyngitis, upper respiratory tract infection, viral upper respiratory tract infection, and pharyngitis.
†Injection site reactions include injection site urticaria, pruritus, pain, reaction, erythema, inflammation, edema, swelling, bruising, hematoma, and hemorrhage.

[…]

Psoriasis of the Nail
The safety of ILUMYA was assessed in a multicenter, randomized, double-blind, placebo controlled trial (Trial 5) in 99 subjects with psoriasis of the nail [*see Clinical Studies (14)*]. No new safety signals were identified through Week 28.

8.2 Immunogenicity
~~As with all therapeutic proteins there is the potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of incidence of antibodies to tildrakizumab in the studies described below with the incidences of antibodies in other studies or to other products may be misleading~~.
The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the studies described below with the incidence of anti-drug antibodies in other studies.

9. USE IN SPECIFIC POPULATIONS

9.1 Pregnancy
Risk Summary
Limited available data with ILUMYA use in pregnant women are insufficient to inform a drug associated risk of adverse developmental outcomes.
Monoclonal antibodies are actively transported across the placenta (see Clinical Considerations) ~~Human IgG is known to cross the placental barrier; therefore, ILUMYA may be transferred from the mother to the fetus~~. An embryofetal developmental study conducted with tildrakizumab in pregnant monkeys revealed no treatment-related effects to the developing fetus when tildrakizumab was administered subcutaneously during organogenesis to near parturition at doses up to 159 times the maximum recommended human dose (MRHD). When dosing was

continued until parturition, an increase in neonatal death was observed at 59 times the MRHD *[see Data below]*. The clinical significance of this nonclinical finding is unknown.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown.

Clinical Considerations
Fetal/Neonatal Adverse Reactions
Transport of endogenous IgG antibodies across the placenta increases as pregnancy progresses, and peaks during the third trimester. Therefore, ILUMYA may be present in infants exposed *in utero*. The potential clinical impact of tildrakizumab exposure in infants exposed *in utero* should be considered.

[…]

14. CLINICAL STUDIES

Psoriasis of the Nail
In a randomized, multicenter, double-blind, placebo-controlled trial (Trial 5 [NCT03897075]), 99 subjects with moderate to severe psoriasis of the nail received subcutaneous ILUMYA 100 mg (N=51) or placebo (N=48) at Weeks 0, 4, and 16. Of the 99 randomized subjects, 78 subjects completed Part 1 (Day 1 to Week 28) of the trial.

The trial population was 79% White, 2% Black or African American, 15% Asian and 4% Other; for ethnicity, 62% of subjects identified as Not Hispanic or Latino. The trial population was 71% male and the mean age was 46 years. At baseline, these subjects had a median Modified Nail Psoriasis Severity Index (mNAPSI) score of 34 and a median PASI score of 16.

The primary endpoint was the proportion of subjects who achieved at least a 75% improvement from baseline in total mNAPSI at Week 28.

The efficacy results from Trial 5 are presented in Table 4.

TABLE 4: Efficacy Results for the Modified Nail Psoriasis Severity Index in Subjects with Moderate to Severe Psoriasis of the Nail in Trial 5 (ITT, NRI*)

	Trial 5	
	ILUMYA 100mg N=51 n (%)	**Placebo N=48 n (%)**
Proportion of subjects who achieve at least a 75% improvement from baseline in total mNAPSI at Week 28	13 (26)	2 (4)

ITT = Intent to Treat.
mNAPSI = modified Nail Psoriasis Severity Index
* NRI = Non-responder Imputation