אוגוסט 2025

Spevigo IV

ספוויגו תוך-ורידי

spesolimab 60 mg/ml

<u>concentrate for solution for infusion</u>

<u>הנדון: עדכון עלונים</u>

רופא/ה יקר/ה, רוקח/ת יקר/ה,

חברת בורינגר אינגלהיים ישראל בע"מ מבקשת להודיעכם על עדכון בעלון לצרכן במתכונת עלון לרופא של התכשיר שבנדון.

ההתוויה הרשומה לתכשיר בישראל:

SPEVIGO is indicated for the treatment of generalized pustular psoriasis (GPP) flares in adults.

השינויים המשמעותיים ביותר בעלונים סומנו מטה.

הסבר:
<u>טקסט עם קו תחתי</u> מציין טקסט שהוסף לעלון.
טקסט עם ~~קו חוצה~~ מציין טקסט שהוסר מן העלון.

למידע נוסף יש לעיין בעלון לצרכן במתכונת עלון לרופא המאושר.
העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות.
כמו כן, ניתן לקבלו על-ידי פנייה לבעל הרישום:
בורינגר אינגלהיים ישראל בע"מ, רח' מדינת היהודים 89 הרצליה פיתוח, ובטלפון 09-9730500.

בברכה,

בת-אל מלכה כהן
רוקחת ממונה
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עדכונים מהותיים בעלון לצרכן במתכונת עלון לרופא

בסעיף **8. WARNINGS AND PRECAUTIONS** עודכן המידע הבא:

8.1 Infections

SPEVIGO may increase the risk of infections. During the one-week placebo-controlled period in the Effisayil-1 trial, infections were reported in 14% of subjects treated with SPEVIGO compared with 6% of subjects treated with placebo *[see Adverse Reactions (9.1)]*.

In patients with a chronic infection or a history of recurrent infection, consider the potential risks and expected clinical benefits of treatment prior to prescribing SPEVIGO. Treatment with SPEVIGO is not recommended ~~for use~~ in patients with any clinically important active infection until the infection resolves or is adequately treated. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur during or after treatment with SPEVIGO. If a patient develops a clinically important active infection, discontinue SPEVIGO therapy until the infection resolves or is adequately treated.

[...]

8.3 Hypersensitivity and Infusion-Related Reactions

SPEVIGO-associated hypersensitivity reactions may include immediate reactions such as anaphylaxis and delayed reactions such as drug reaction with eosinophilia and systemic symptoms (DRESS).

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported in clinical trials with ~~spesolimab~~ SPEVIGO in subjects with GPP *[see Adverse Reactions (9.1)]*.

If a patient develops signs of anaphylaxis or other serious hypersensitivity, discontinue SPEVIGO immediately and initiate appropriate treatment. SPEVIGO is contraindicated in patients with hypersensitivity to spesolimab or to any of the excipients in SPEVIGO *[see Contraindications (7)]*.

If a patient develops mild or moderate hypersensitivity during an intravenous infusion or other infusion-related reactions, stop SPEVIGO infusion and consider appropriate medical therapy (e.g., systemic antihistamines and/or corticosteroids). Upon resolution of the reaction, the infusion may be restarted at a slower infusion rate with gradual increase to complete the infusion.

8.4 Vaccinations

Avoid use of live vaccines in patients during and for at least 16 weeks after treatment ~~treated~~ with SPEVIGO. No specific studies have been conducted in SPEVIGO-treated patients who have recently received live viral or live bacterial vaccines.

[...]

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בסעיף **9. ADVERSE REACTIONS** עודכן המידע הבא:

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Infections *[see Warnings and Precautions (8.1)]*
- Hypersensitivity and Infusion-Related Reactions *[see Warnings and Precautions (8.3)]*

[...]

בסעיף **10. USE IN SPECIFIC POPULATIONS** עודכן המידע הבא:

10.1 Pregnancy

Risk Summary

The limited data on the use of SPEVIGO in pregnant women are insufficient to inform a drug-associated risk of adverse pregnancy-related outcomes. Human IgG is known to cross the placental barrier; therefore, SPEVIGO may be transmitted from the mother to the developing fetus. In an animal reproduction study, intravenous administration of a surrogate antibody against IL36R in mice during the period of organogenesis did not elicit any reproductive toxicity *(see Data)*.

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

[...]

בסעיף **12. CLINICAL PHARMACOLOGY** עודכן המידע הבא:

[...]

12.3 Pharmacokinetics

[...]

Drug Interaction Studies

No formal drug interactions studies have been conducted with spesolimab. In patients with GPP, spesolimab is not expected to cause cytokine-mediated CYP interactions as a perpetrator.

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