אוגוסט 2026
רופא/ה רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא של התכשיר:

Vyepti

חומר פעיל:
EPTINEZUMAB 100 MG / 1 ML

להלן עדכונים מהותיים בלבד בעלון לרופא (כל השינויים והמחיקות מסומנים בפורמט Track Changes):

SUMMARY OF PRODUCT CHARACTERISTICS

[...]

5.3. Infusion Administration Instructions

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if the liquid contains visible particulate matter or is cloudy or discolored *[see PHARMACEUTICAL FORM ~~QUALITATIVE AND QUANTITATIVE COMPOSITION~~(32)]*.

[...]

7. WARNINGS AND PRECAUTIONS

[...]

7.2. Constipation with Serious Complications

Constipation with serious complications has been reported following the use of monoclonal antibody CGRP antagonists, including VYEPTI, in the postmarketing setting. There were cases with monoclonal antibody CGRP antagonists that required hospitalization, including cases where surgery was necessary. In a majority of these cases, the onset of constipation was reported after the first dose; however, patients have also presented with constipation later on in treatment. The monoclonal antibody CGRP antagonist was discontinued in many of the reported cases of constipation with serious complications.

Monitor patients treated with VYEPTI for severe constipation and manage as clinically appropriate. The concurrent use of medications that reduce gastrointestinal motility may increase the risk for more severe constipation and the potential for constipation-related complications.

[...]

8. ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Hypersensitivity Reactions *[see WARNINGS AND PRECAUTIONS (7.1)]*.
- Constipation with Serious Complications [see *WARNINGS AND PRECAUTIONS* (7.2)]
- Hypertension *[see WARNINGS AND PRECAUTIONS (7.32)]*
- Raynaud's Phenomenon *[see WARNINGS AND PRECAUTIONS (7.43)]*

8.1. Clinical Trials Experience

[...]

In Study 3, the safety profile observed in 480 patients who were randomized and treated (238 to VYEPTI 100 mg and 242 to placebo) was consistent with the safety profile observed in the two pivotal placebo-controlled studies with VYEPTI (Study 1 and Study 2).

~~8.2 Immunogenicity~~

~~As with all therapeutic proteins, there is 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 the incidence of antibodies to eptinezumab in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.~~

~~In patients receiving VYEPTI 100 mg or 300 mg every 3 months, the incidence of anti-eptinezumab antibody development in Study 1 (up to 56 weeks) was 20.6% (92/447), and 41.3% (38/92) of those patients developed anti-eptinezumab neutralizing antibodies. In Study 2 (up to 32 weeks), the incidence of anti-eptinezumab antibody development was 18.3% (129/706), and 34.9% (45/129) of those patients developed anti-eptinezumab neutralizing antibodies. In an open-label study with 84 weeks of treatment, 18% (23/128) of patients developed anti-eptinezumab antibodies, and 39% (9/23) of those patients developed anti-eptinezumab neutralizing antibodies.~~

~~Although the results from both studies showed no clear evidence of an impact from development of anti-eptinezumab antibodies, including neutralizing antibodies, on the safety and efficacy profiles of VYEPTI, the available data are too limited to make definitive conclusions.~~

8.28.3 POSTMARKETING EXPERIENCE

The following adverse reactions have been identified during postapproval use of VYEPTI. Because these reactions are reported voluntarily from a population of

uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Gastrointestinal Disorders: Constipation [see WARNINGS AND PRECAUTIONS (7.2)]
~~*Immune System Disorders:* Anaphylaxis *[see CONTRAINDICATIONS (6) and WARNINGS AND PRECAUTIONS (7.1)].*~~
General Disorders and Administration Site Conditions: Fatigue
Immune System Disorders: Anaphylaxis *[see CONTRAINDICATIONS (6) and WARNINGS AND PRECAUTIONS (7.1)].*

Vascular Disorders: Hypertension *[see WARNINGS AND PRECAUTIONS (7.~~3~~2)]*, Raynaud's phenomenon *[see WARNINGS AND PRECAUTIONS (7.~~4~~3)]*

[...]

11. CLINICAL PHARMACOLOGY

[...]

11.4. Immunogenicity

~~As with all therapeutic proteins, there is potential for immunogenicity.~~ The observed incidence of anti-drug antibodies ~~detection of antibody formation~~ is highly dependent on the sensitivity and specificity of the assay. ~~Additionally, the observed incidence of antibody (including neutralizing antibody) positivi~~Differencesty in ~~an~~ assay methods preclude meaningful ~~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 the incidence of anti-drug antibodies ~~to eptinezumab~~ in the studies described below with the incidence of anti-drug antibodies in other studies, including those of eptinezumab. ~~or to other products may be misleading.~~

In patients receiving VYEPTI 100 mg or 300 mg every 3 months, the incidence of anti-eptinezumab antibody development in Study 1 (up to 56 weeks) was 20.6% (92/447), and 41.3% (38/92) of those patients developed anti-eptinezumab neutralizing antibodies. In Study 2 (up to 32 weeks), the incidence of anti-eptinezumab antibody development was 18.3% (129/706), and 34.9% (45/129) of those patients developed anti-eptinezumab neutralizing antibodies. In an open-label study with 84 weeks of treatment, 18% (23/128) of patients developed anti-eptinezumab antibodies, and 39% (9/23) of those patients developed anti-eptinezumab neutralizing antibodies.

Although the results from both studies showed no clear evidence of an impact from

development of anti-eptinezumab antibodies, including neutralizing antibodies, on the safety and efficacy profiles of VYEPTI, the available data are too limited to make definitive conclusions.

[...]

13. CLINICAL STUDIES

The efficacy of VYEPTI was evaluated in three~~as a preventive treatment of episodic and chronic migraine in two~~ randomized, multicenter, placebo-controlled double-blind studies that enrolled patients with episodic and chronic migraine who were eligible for preventive treatment of migraine. In Study 1, which included~~, both with 6-month double-blind periods: one study in~~ patients with episodic migraine~~.~~, and Study 2, which included ~~(Study 1) and one study in~~ patients with chronic migraine ~~(Study 2)~~, either 100 mg or 300 mg~~.~~ VYEPTI was administered by intravenous infusion every 3 months. In Study 3, 100 mg VYEPTI was administered as a single intravenous infusion to patients with episodic or chronic migraine who were eligible for preventive migraine treatment and who had a concurrent migraine. ~~in both studies; however, the primary endpoint was measured at 12 weeks.~~

[...]

Study 3: Episodic Migraine or Chronic Migraine
Study 3 (NCT04152083~~NCT01719055~~) included adults who were candidates for preventive migraine therapy with VYEPTI and presented with a concurrent moderate to severe migraine on the day of infusion. A total of 480 patients were randomized to receive 100 mg VYEPTI (n=238) or placebo (n=242) as a single dose. VYEPTI demonstrated statistically significant improvements in headache pain freedom at 2 hours (VYEPTI 23.5% vs placebo 12%; p<0.001) and absence of most bothersome symptom (such as nausea, photophobia, or phonophobia) at 2 hours (VYEPTI 55.5% vs placebo 35.8%;
p< 0.001) as compared to placebo. The dose of 300 mg VYEPTI was not evaluated in Study 3.

[...]

16. License Holder:

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17. Registration Number: 168-65-36769-00

Revised in August ~~March~~ 2026.

העלון לרופא ולצרכן נשלח למאגר התרופות שבאתר משרד הבריאות www.health.gov.il לצורך העלאתו לאתר וניתן לקבלם מודפסים על ידי פניה לבעל הרישום.

בברכה
חגי וגנר
רוקח ממונה