

חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר

AJOVY אג'ובי

תמיסה להזרקה תת-עורית

שם וכמות חומר פעיל

Fremanezumab 225 mg/1.5 ml

עדכונים בעלון לצרכן

התוויה כפי שאושרה בתעודת הרישום:

AJOVY is indicated for prophylaxis of migraine in adults who have at least 4 migraine days per month.

ברצוננו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Calcitonin gene-related peptide (CGRP) antagonists.

ATC code: N02CD03.

[...]

Difficult to treat migraine

The efficacy and safety of fremanezumab in a total of 838 episodic and chronic migraine patients with documented inadequate response to two to four classes of prior migraine preventive medicinal products was assessed in a randomised study (Study 4), which was composed of a 12-week double-blind, placebo-controlled treatment period followed by a 12-week open-label period.

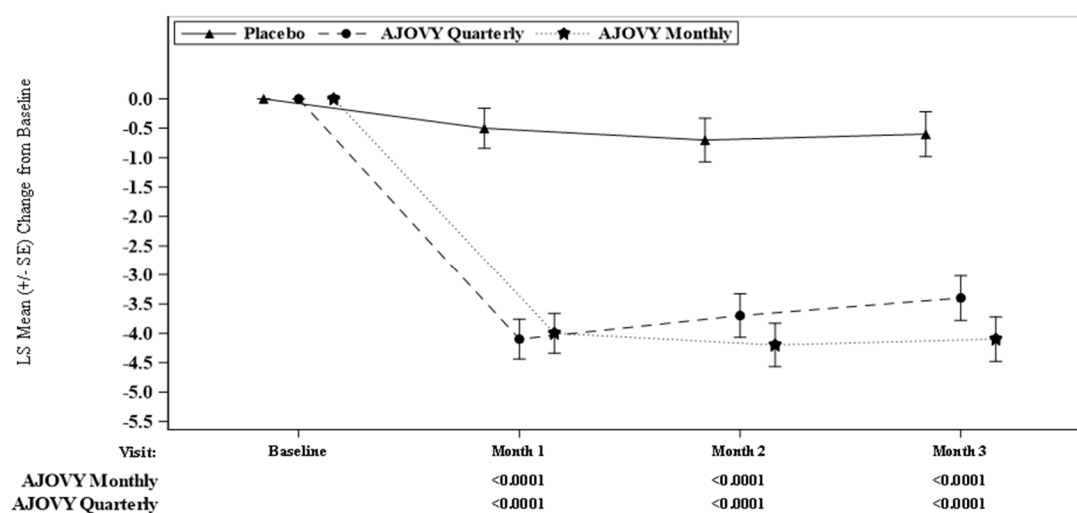
The primary efficacy endpoint was the mean change from baseline in the monthly average number of migraine days during the 12-week double-blind treatment period. Key secondary endpoints were the



achievement of at least 50% reduction from baseline in monthly migraine days, the mean change from baseline in the monthly average number of headache days of at least moderate severity and change from baseline in monthly average number of days of acute headache medicinal product use. Both monthly and quarterly dosing regimens of fremanezumab demonstrated statistically significant and clinically meaningful improvement from baseline compared to placebo for key endpoints. Therefore, the results of Study 4 are consistent with the main findings of the previous efficacy studies and in addition demonstrate efficacy in difficult to treat migraine, including mean reduction in monthly migraine days (MMD) of -3.7 (95% CI: -4.38, -3.05) with fremanezumab quarterly and -4.1 (95% CI: -4.73, -3.41) with fremanezumab monthly compared to -0.6 (95% CI: -1.25, 0.07) in placebo-treated patients. 34% of the patients treated with fremanezumab quarterly and 34% of the patients treated with fremanezumab monthly achieved at least 50% reduction in MMD, compared to 9% in placebo-treated patients ($p < 0.0001$) during the 12-week treatment period. The effect also occurred from as early as the first month and was sustained over the treatment period (see Figure 3). No safety signal was observed during the 6-month treatment period.

[...]

Figure 3: Mean Change from Baseline in Monthly Average Number of Migraine Days for Study 4



Mean at baseline (monthly average number of migraine days): Placebo: 14.4, AJOVY Quarterly: 14.1, AJOVY Monthly: 14.1.

[...]

העלון לצרכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות

וניתן לקבלו מודפס ע"י פניה לחברת טבע. <http://www.health.gov.il>