

03/2025

# Margenza

## מרג'נזה

### MARGETUXIMAB 25 MG/ML

#### Concentrate for Solution for Infusion, I.V.

רופא/ה, חוקח/ת נכבד/ה,  
חברת ניאופרם בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנידון.  
העלון עודכן בתאריך 03/2025.

ההתוויה הרשומה לתכשיר בישראל:

MARGENZA is indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

בהודעה זו מצוינים עדכונים מהותיים בלבד בעלון לרופא:

מידע שעבר מקום - כתב ירוק  
מידע שעבר מקום והוסר - כתב ירוק עם קו-חוצה  
תוספת מידע - כתב כחול

#### 6.2 10.4 Immunogenicity

~~As with all therapeutic proteins, there is potential for immunogenicity with MARGENZA. The detection of antibody formation is highly dependent on assay sensitivity and specificity. 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 MARGENZA in the studies described below with the incidence of antibodies in other studies or to other products may be misleading.~~

~~In SOPHIA, samples were obtained from patients on MARGENZA for immunogenicity testing at baseline, every 2 cycles, and at end of study therapy. All patients enrolled in SOPHIA received trastuzumab previously, and treatment emergent anti-margetuximab antibodies were observed in 4 patients (1.7%). Of these 4 patients, anti-margetuximab antibodies were detected prior to Cycle 7 of MARGENZA dosing in 1 patient, and more than 2 months after the last MARGENZA dose in 3 patients. In the infusion substudy, treatment emergent anti-margetuximab antibodies were observed in 2 patients (3.8%). Of these 2 patients, anti-margetuximab antibodies were detected prior to Cycle 3 of MARGENZA dosing in 1 patient, and more than 6 months after the last MARGENZA dose in 1 patient. Due to the limited number of patients who developed anti-margetuximab antibodies during treatment with MARGENZA, the impact of anti-margetuximab antibodies on the PK, safety and efficacy of MARGENZA is unknown. **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, including those of MARGENZA or of other margetuximab products.**~~

**In patients who received MARGENZA in combination with chemotherapy in SOPHIA (up to 68 months) or the Infusion substudy (up to 42 months), the incidence of anti-margetuximab antibodies was 2% (7/350). No patients developed treatment-emergent neutralizing antibodies.**

**Given the low incidence of anti-margetuximab antibodies, the effect of anti-margetuximab antibodies on the pharmacokinetics, pharmacodynamics, safety, and/or effectiveness of margetuximab-cmkb is unknown.**

**קיימים בעלון עדכונים נוספים, למידע נוסף יש לעיין בעלון לרופא המעודכן.**

העלון נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פניה לבעל הרישום:  
ניאופרם בע"מ, ת.ד. 7063, פתח תקווה 4917001.  
טלפון: 03-9373753, פקס: 03-9373774

בברכה  
עוז וולך, רוקח/ת ממונה של בעל הרישום