מאי 2019

# Perjeta® 420mg/14ml
# פרג'טה 420 מ"ג /14 מ"ל
# Pertuzumab
# Concentrate for solution for infusion

רופא/ה יקר/ה, רוקח/ת יקר/ה,

חברת רוש פרמצבטיקה (ישראל) בע"מ מבקשת להודיעכם על מספר עדכונים בעלון לרופא של התכשיר פרג'טה. בהודעה זו מצוינים רק עדכונים מהותיים ועדכונים אשר מהווים החמרה.

**ההתוויות הרשומות לתכשיר בישראל:**

**Metastatic Breast Cancer:**
Perjeta is indicated in combination with trastuzumab and docetaxel for the treatment of patients with HER2 positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

**Early breast cancer:**
Perjeta is indicated for use in combination with trastuzumab and docetaxel for the neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or arly stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. This indication is based on demonstration of an improvement in pathological complete response rate. No data are available demonstrating improvement in event-free survival or overall.

Perjeta is indicated for use in combination with trastuzumab and chemotherapy for the adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence (positive nodes).

**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 לרופא כפי שאושר ע"י משרד הבריאות.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס ע"י פנייה לבעל הרישום: רוש פרמצבטיקה (ישראל) בע"מ, ת.ד 6391 , הוד השרון 4524079
טלפון 09-9737777. כתובתנו באינטרנט: www.roche.co.il.

ב ב ר כ ה,

אביטל ויסברוט
מחלקת רישום

לילי אדר
רוקחת ממונה

# עדכונים מהותיים בעלון לרופא

**בסעיף 4.4 Special warnings and precautions for use עודכן המידע הבא:**

Infusion reactions

Perjeta has been associated with infusion reactions, including events with a fatal outcome (see section 4.8). Close observation of the patient during and for 60 minutes after the first infusion and during and for 30-60 minutes after subsequent infusions of Perjeta is recommended. If a significant infusion reaction occurs, the infusion should be slowed down or interrupted and appropriate medical therapies should be administered. Patients should be evaluated and carefully monitored until complete resolution of signs and symptoms. Permanent discontinuation should be considered in patients with severe infusion reactions. This clinical assessment should be based on the severity of the preceding reaction and response to administered treatment for the adverse reaction.

Hypersensitivity reactions/anaphylaxis

Patients should be observed closely for hypersensitivity reactions. Severe hypersensitivity, including anaphylaxis and events with a fatal outcome, has been observed ~~in clinical trials~~ with Perjeta (see section 4.8). Medicinal products to treat such reactions, as well as emergency equipment, should be available for immediate use. Perjeta must be permanently discontinued in case of NCI-CTCAE Grade 4 hypersensitivity reactions (anaphylaxis), bronchospasm or acute respiratory distress syndrome

**בסעיף 4.8 Undesirable effects עודכן המידע הבא:**

Table 2 Summary of ADRs in patients treated with Perjeta in clinical trials, and in the Post-marketing setting

[…]

* ADRs with a fatal outcome have been reported.
** For the overall treatment period across the 4 studies. The incidence of left ventricular dysfunction and cardiac failure congestive reflect the MedDRA Preferred Terms reported in the individual studies.
° Hypersensitivity/anaphylactic reaction is based on a group of terms.
°° Infusion reaction includes a range of different terms within a time window, see “Description of selected adverse reactions” below.
† ADRs reported in the post marketing setting-