

פברואר 2022

Kanjinti 150/420 (Trastuzumab)
Powder for concentrate for solution for infusion

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

אמג'ן אירופה בי.וי., בעלת הרישום, מבקשת להודיעך על עדכונים בעלון לרופא לתכשיר קנג'ינטי. בהודעה זו מצוינים עדכונים מהותיים בלבד. קו תחתי מציין תוספת טקסט, קו חוצה מציין מחיקת טקסט.

ההתוויות הרשומות לתכשיר:

Metastatic breast cancer (MBC)

KANJINTI is indicated for the treatment of patients with metastatic breast cancer who have tumors that overexpress HER2;

1. As a single agent, for the treatment of those patients who have received one or more chemotherapy regimens for their metastatic disease.
2. In combination with Paclitaxel or Docetaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease.
3. In combination with an aromatase inhibitor for the treatment of postmenopausal patient with hormone-receptor positive metastatic breast cancer.

Early breast cancer (EBC)

KANJINTI is indicated to treat patients with HER2-positive early breast cancer following surgery and chemotherapy (neoadjuvant or adjuvant) either alone or in combination with chemotherapy excluding anthracyclines.

KANJINTI should only be used in patients whose tumors have either HER2 overexpression or HER2 gene amplification as determined by an accurate and validated assay.

HER2 Metastatic gastric cancer (MGC)

KANJINTI in combination with capecitabine or 5-fluorouracil and cisplatin is indicated for the treatment of patients with HER2-positive metastatic adenocarcinoma of the stomach or gastroesophageal junction who have not received prior anti-cancer treatment for their metastatic disease.

KANJINTI should only be used in patients with metastatic gastric cancer whose tumors have HER2 overexpression as defined by IHC 2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay.

עדכונים בעלון לרופא:

4.2 Posology and method of administration

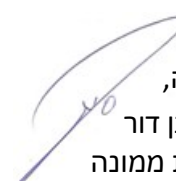
[...]

In order to prevent medication errors it is important to check the vial labels to ensure that the drug being prepared and administered is KANJINTI (trastuzumab) and not another trastuzumab-containing product Kadcyla (e.g. trastuzumab emtansine or trastuzumab deruxtecan).

העלון לרופא המעודכן נשלח לפרסום במאגר התרופות של אתר משרד הבריאות, וניתן לקבלו גם על-ידי פניה למפיץ המקומי של התרופה, חברת נובולוג.

לפרטים ולהזמנות:

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- מייל: Sales@medomie.co.il


 בברכה,
 סיגל בן דור
 רוקחת ממונה