אוגוסט 2021

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 השינויים העיקריים בלבד.

ההתוויות המאושרות:

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 מהותיים בעלון לרופא:

4.6 Fertility, pregnancy and lactation

[...]

Breast-feeding

A study conducted in ~~lactating~~ cynomolgus monkeys at doses 25 times that of the weekly human maintenance dose of 2 mg/kg trastuzumab intravenous formulation from days 120 to 150 of pregnancy demonstrated that trastuzumab is secreted in the milk postpartum. The exposure to trastuzumab in utero and the presence of trastuzumab in the serum of infant monkeys was not associated with any adverse effects on their growth or development from birth to 1 month of age. It is not known whether trastuzumab is secreted in human milk. As human IgG1 is secreted into human milk, and the potential for harm to the infant is unknown, women should not breast-feed during KANJINTI therapy and for 7 months after the last dose.

6.6 Special precautions for disposal and other handling

[…]

The appropriate amount of solution should be withdrawn from the vial using a sterile needle and syringe and added to an infusion bag containing 250 mL of sodium chloride 9 mg/mL (0.9%) solution for injection. Do not use with glucose-containing solutions (see section 6.2). The bag should be gently inverted to mix the solution in order to avoid foaming.

העלון לרופא המעודכן נשלח לפרסום במאגר התרופות של אתר משרד הבריאות, ניתן לקבלו גם על-ידי פניה למפיץ המקומי: חברת נובלוג.

לפרטים ולהזמנות;

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בברכה,

סיגל בן דור

רוקחת ממונה