אוניפארם סחר unipharm trading

רופא /ה, רוקח/ת נכבד/ה יוני ,2022

<u>הודעה על עדכון עלון לרופא</u>

HERITY הריטי

Powder and solvent for concentrate for solution for infusion

חברת אוניפארם סחר בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשיר **הריטי**.

בפירוט שלהלן כלולים העדכונים המהותיים בלבד. עדכונים שאינם מהותיים, אינם כלולים בהודעה זו.
למידע מלא, יש לעיין בעלון. תוספות המידע מסומנות בצבע כחול, החמרות מודגשות בצהוב והסרות המידע מופיעות בקו חוצה.

מרכיב פעיל:

Trastuzumab 420 mg/vial

ההתוויה המאושרת:

Herity is indicated for the treatment of patients with metastatic breast cancer who have tumours that overexpress HER2:
1. As a single agent for the treatment of those patients who have received one or more chemotherapy regiments 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. Herity in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive metastatic breast cancer.
Early breast cancer (EBC):
Herity 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.
Herity 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):
Herity 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 gastro-esophageal junction who have not received prior anti-cancer treatment for their metastatic disease.
Herity should only be used in patients with metastatic gastric cancer whose tumours have HER2 overexpression as defined by IHC2+ 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 trastuzumab and not another trastuzumab-containing product (e.g trastuzumab emtansine or trastuzumab deruxtecan).

[…]

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 trastuzumab therapy and for 7 months after the last dose.

[…]

6.6. Instructions for use and handling

[…]

Reconstitution:
[…]
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 0.9 % sodium chloride solution. Do not use with glucose-containing solutions (see section 6.2).
[…]