מרץ 2024

רופא/ה רוקח/ת נכבד/ה,

חברת פאדאגיס מבקשת ליידע אתכם על עדכון העלון לרופא של התכשירים:

Herzuma 150 mg / Herzuma 420 mg

הרצומה 420 מ"ג / הרצומה 150 מ"ג

החומר הפעיל בתכשירים וחוזקו:
Trastuzumab 150 mg / 1 vial (for Herzuma 150 mg)
Trastuzumab 420 mg / 1 vial (for Herzuma 420 mg)

<u>התוויה הרשומה לתכשירים בישראל:</u>

Herzuma 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 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) ;
Herzuma 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. Herzuma should only be used in patients whose tumours have either HER2 overexpression or HER2 gene amplification as determined by an accurate and validated assay.
HER2 Metastatic Gastric Cancer (mGC);
Herzuma 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 .
Herzuma 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.

<u>מהות העדכון</u>:
בהודעה זו מצוינים ומסומנים ברקע צהוב העדכונים הרלוונטיים. העלונים כוללים גם עדכונים נוספים אשר אינם נחשבים כמהותיים.

העלונים המעודכנים לצרכן ולרופא נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
<u>https://israeldrugs.health.gov.il</u>

בברכה,
פאדאגיס ישראל סוכנויות בע"מ

עלון לרופא

6.3 Shelf life

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Shelf-life following reconstitution and dilution;

Stability of ready infusion solution of Herzuma 150 mg and Herzuma 420 mg when reconstituted with Sterile Water for Injection (SWI):
After aseptic dilution in polyvinylchloride, polyethylene or polypropylene bags containing sodium chloride 9 mg/mL (0.9%) solution for injection, chemical and physical stability of Herzuma has been demonstrated for up to ~~48 hours~~30 days at 2°C-8°C, and 24 hours at temperatures not exceeding 30ºC.

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6.6 Instructions for use and handling

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Instructions for aseptic reconstitution

1) Using a sterile syringe, slowly inject the appropriate volume (as noted above) of sterile water for injection/ bacteriostatic water for injection in the vial containing the lyophilised Herzuma, directing the stream into the lyophilised cake.

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