אוגוסט 2021

Ogivri 420 mg,
Powder and Solvent for Concentrate for Solution for Infusion

צוות רפואי נכבד,

חברת דקסל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשיר **אוגיברי 420 מ"ג**.
בהודעה זו מפורטים עדכונים מהותיים ועדכונים המהווים החמרה במידע הבטיחותי בלבד. למידע מלא, יש לעיין בעלון.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פנייה לבעל הרישום: דקסל בע"מ, רח' דקסל 1, אור עקיבא 3060000, ישראל, טל': 04-6364000.

הרכב התכשיר:

Each package contains two vials:
Trastuzumab 420mg/vial + Bacteriostatic Water for Injection 20 ml

ההתוויות המאושרות:

Ogivri 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. In combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormonereceptor positive metastatic breast cancer.
Early breast cancer (EBC):
Ogivri 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.
Ogivri 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).
Ogivri 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.
Ogivri 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.

העלון לרופא עודכן באוגוסט 2021. להלן העדכונים (מסומנים באדום):

6.6 Instructions for use and handling

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The appropriate amount of solution should be withdrawn from the vial using a sterile needle and syringe and added to an infusion bag containing 250 ml of 0.9 % sodium chloride solution.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). The bag should be gently inverted to mix the solution in order to avoid foaming.

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