אוגוסט 2018

HERCEPTIN® (Trastuzumab) 440 mg I.V

Solution for I.V. infusion

רופא/ה יקר/ה, רוקח/ת יקר/ה,

חברת רוש פרמצבטיקה (ישראל) בע"מ מבקשת להודיעכם על מספר עדכונים בעלון לרופא של התכשיר הרספטין. בהודעה זו מצוינים רק עדכונים מהותיים ועדכונים אשר מהווים החמרה.

ההתוויה הרשומה לתכשיר בישראל:

Metastatic Breast Cancer (MBC)

Herceptin 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)

Herceptin 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.

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

HER-2 Metastatic Gastric Cancer (MGC)

Herceptin 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.

Herceptin 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.

הסבר:

טקסט עם קו תחתי מציין טקסט שהוסף לעלון.

~~טקסט עם קו חוצה~~ מציין טקסט שהוסר מן העלון.

למידע נוסף יש לעיין בעלון לרופא כפי שאושר על ידי משרד הבריאות.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על-ידי פנייה לבעל הרישום: רוש פרמצבטיקה (ישראל) בע"מ, ת.ד. 6391, הוד השרון 4524079 , טלפון 09-9737777. כתובתנו באינטרנט: www.roche.co.il.

ב ב ר כ ה,

אביטל ויסברוט
מחלקת רישום

לילי אדר
רוקחת ממונה

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עדכונים מהותיים בעלון לרופא

בסעיף 4.4 Special warnings and precautions for use עודכן המידע הבא:

[…]

Neoadjuvant-adjuvant treatment

[…]

In the pivotal trial BO22227, Herceptin was administered concurrently with neoadjuvant chemotherapy that contained four cycles of epirubicin (cumulative dose 300 mg/m^2); at a median follow-up ~~of 40~~ exceeding 70 months, the incidence of cardiac failure/congestive cardiac failure was 0.~~0~~3% in the Herceptin intravenous arm and 0.7% in the Herceptin subcutaneous arm. In patients with lower body weights (<59 kg, the lowest body weight quartile) the fixed dose used in the Herceptin subcutaneous arm was not associated with an increased risk of cardiac events or significant drop in LVEF.

בסעיף 4.7 Effects on ability to drive and use machines עודכן המידע הבא:

Herceptin ~~has no or negligible~~ may have a minor influence on the ability to drive or use machines, (see section 4.8). However, patients experiencing administration-related symptoms (see section 4.4) should be advised not to drive and use machines until symptoms abate.

בסעיף 4.8 Undesirable effects עודכן המידע הבא:

[…]

Immunogenicity

In the neoadjuvant-adjuvant EBC ~~treatment setting, 8.1 %~~ study (BO22227), at a median follow-up exceeding 70 months, 10.1% (~~24~~30/296) of patients treated with Herceptin intravenous and ~~14~~.9 % (~~44~~47/295) of patients receiving Herceptin subcutaneous vial developed antibodies against trastuzumab ~~(regardless of antibody presence at baseline).~~ Neutralizing anti-trastuzumab antibodies were detected in post-baseline samples in 2 of ~~24~~ 30 Herceptin intravenous and 4 of ~~44~~7 in the Herceptin subcutaneous ~~vial patients~~arm. ~~20~~21.0 % of patients treated with Herceptin subcutaneous formulation developed antibodies against the excipient hyaluronidase (rHuPH20).

The clinical relevance of these antibodies is not known~~; nevertheless the~~. The presence of anti-trastuzumab antibodies had no impact on pharmacokinetics, efficacy (determined by pathological Complete Response [pCR] and event free survival [EFS]) and safety determined by occurrence of administration related reactions (ARRs) of Herceptin intravenous and Herceptin subcutaneous ~~did not appear to be adversely affected by these antibodies~~.

Details of risk minimisation measures that are consistent with the EU Risk Management Plan are presented in Section 4.4.