מרץ 2018

Perjeta® 420mg/14ml
פרג'טה 420 מ"ג /14 מ"ל
Pertuzumab
Concentrate for solution for infusion

רופא/ה יקר/ה, רוקח/ת יקר/ה,

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

ההתוויות הרשומות לתכשיר בישראל:

Metastatic Breast Cancer
Perjeta is indicated in combination with trastuzumab and docetaxel for the treatment of patients with HER2 positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

Neoadjuvant Treatment of Breast Cancer
Perjeta is indicated for use in combination with trastuzumab and docetaxel for the neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. This indication is based on demonstration of an improvement in pathological complete response rate. No data are available demonstrating improvement in event-free survival or overall.
Limitations of Use:

- The safety of Perjeta as part of a doxorubicin-containing regimen has not been established.
- The safety of Perjeta administered for greater than 6 cycles for early breast cancer has not been established.

הסבר:

<u>טקסט עם קו תחתי</u> מציין טקסט שהוסף לעלון.
~~טקסט עם קו חוצה~~ מציין טקסט שהוסר מן העלון.

למידע נוסף יש לעיין בעלון לרופא כפי שאושר ע"י 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

עדכונים מהותיים בעלון לרופא

בסעיף 4.2 Posology and method of administration עודכן המידע הבא:

Hypersensitivity reactions/anaphylaxis

The infusion should be discontinued immediately and permanently if the patient experiences a NCI-CTCAE Grade 4 reaction (anaphylaxis), bronchospasm or acute respiratory distress syndrome (see section 4.4).

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

On the basis of reported adverse reactions, Perjeta ~~is not expected to~~ has no or negligible influence the ability to drive or use machines. Patients experiencing infusion reactions should be advised not to drive and use machines until symptoms abate.

בסעיף 4.8 Undesirable effects עודכן המידע הבא:

[…]

~~Metastatic Breast Cancer~~

~~In the pivotal clinical trial CLEOPATRA, 408 patients received at least one dose of Perjeta in combination with trastuzumab and docetaxel. The most common ADRs (≥ 50%) seen with Perjeta in combination with trastuzumab and docetaxel were diarrhoea, alopecia and neutropenia. The most common NCI-CTCAE v.3 Grade 3-4 ADRs (> 10%) were neutropenia, febrile neutropenia and leucopenia, and the most common serious adverse events were febrile neutropenia, neutropenia and diarrhoea. Treatment-related deaths occurred in 1.2% of patients in the Perjeta-treated group and 1.5% of patients in the placebo-treated group and were mainly due to febrile neutropenia and/or infection.~~

~~In the pivotal trial CLEOPATRA, ADRs were reported less frequently after discontinuation of docetaxel treatment. After discontinuation of docetaxel, ADRs in the Perjeta and trastuzumab treated group occurred in < 10% of patients with the exception of diarrhoea (28.1%), upper respiratory tract infection (18.3%), rash (18.3%), headache (17.0%), fatigue (13.4%), nasopharyngitis (17.0%), asthenia (13.4%), pruritus (13.7%), arthralgia (11.4%), nausea (12.7%), pain in extremity (13.4%), back pain (12.1%) and cough (12.1%).~~

~~Neoadjuvant Treatment of Breast Cancer~~

~~In the neoadjuvant trial NEOSPHERE, the most common ADRs (≥50%) seen with Perjeta in combination with trastuzumab and docetaxel were alopecia and neutropenia. The most common NCI-CTCAE v.3 Grade 3-4 ADR (≥10%) was neutropenia.~~

~~In the neoadjuvant trial TRYPHAENA, when Perjeta was administered in combination with trastuzumab and FEC (5-fluorouracil, epirubicin, cyclophosphamide) for 3 cycles followed by 3 cycles of Perjeta, trastuzumab and docetaxel , the most common ADRs (≥50%) were neutropenia, diarrhea and nausea. The most common NCI-CTCAE v.3 Grade 3-4 ADRs (≥10%) were neutropenia, febrile neutropenia and leucopenia. When Perjeta was administered in combination with trastuzumab and docetaxel for 3 cycles following 3 cycles of FEC (5-fluorouracil, epirubicin, cyclophosphamide), the most common ADRs (≥50%) were diarrhoea, nausea and alopecia. The most common NCI-CTCAE v.3 Grade 3-4 ADRs (≥10%) were neutropenia and leucopenia. Similarly, when Perjeta was administered in~~

~~combination with TCH (docetaxel, carboplatin and trastuzumab) for 6 cycles, the most common ADRs (≥50%) were diarrhoea and alopecia. The most common NCI-CTCAE v. 3 Grade 3-4 ADRs (≥10%) were neutropenia, febrile neutropenia, anaemia, leucopenia and diarrhoea. The safety of Perjeta administered for more than 6 cycles in the neoadjuvant setting has not been established.~~

~~In the BERENICE trial, when Perjeta was administered in combination with trastuzumab and paclitaxel for four cycles following four cycles of two weekly doxorubicin and cyclophosphamide (dose dense AC), the most common ADRs (≥50%) were nausea, diarrhoea, fatigue and alopecia. The most common NCI-CTCAE (v.4) Grade 3-4 ADR (≥10%) was neutropenia. When Perjeta was administered in combination with trastuzumab and docetaxel for four cycles following four cycles of FEC the most common ADRs (≥50%) were nausea, diarrhea and alopecia. The most common NCI-CTCAE (v.4) Grade 3-4 ADRs (≥10%) were febrile neutropenia and diarrhoea. The overall safety profile seen in BERENICE is consistent with that observed in previous data in the neoadjuvant setting for NEOSPHERE and TRYPHAENA.~~