אוגוסט 2024

Phesgo® (Pertuzumab and Trastuzumab)

פסגו

Solution for Subcutaneous Injection

רופא/ה יקר/ה, רוקח/ת יקר/ה,

חברת רוש פרמצבטיקה (ישראל) בע"מ מבקשת להודיעכם על מספר עדכונים בעלון לרופא של התכשיר פסגו.

בהודעה זו מצוינים רק עדכונים מהותיים ועדכונים אשר מהווים החמרה.

ההתוויות הרשומות בישראל:

Early breast cancer (EBC)

Phesgo is indicated for use in combination with chemotherapy 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.
- The adjuvant treatment of patients with HER2-positive early breast cancer (node positive) at high risk of recurrence.

Metastatic breast cancer (MBC)

Phesgo is indicated for use in combination with 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.

הסבר:

טקסט עם קו תחתי מציין טקסט שהוסף לעלון.

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

טקסט עם קו תחתי ~~וקו חוצה~~ מציין טקסט שמיקומו בעלון השתנה.

למידע נוסף יש לעיין בעלון לרופא ובעלון לצרכן כפי שאושרו ע"י משרד הבריאות.

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים 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.

חברת רוש עומדת לרשותך בכל שאלה בנושא.

ב ב ר כ ה,

דר' ענבל וינוגרד
רוקחת ממונה

אביטל ויסברוט
מחלקת רישום

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עדכונים מהותיים בעלון התכשיר

4.8 Undesirable effects

[…]

The safety profile of Phesgo was overall consistent to the known safety profile of intravenous pertuzumab in combination with trastuzumab, with an additional ADR of injection site reaction (~~14.9~~15.3 % vs. 0.4 %).

In the pivotal trial FEDERICA, SAEs were equally distributed between the Phesgo treatment arm and the intravenous pertuzumab in combination with trastuzumab treatment arm. The following adverse drug reactions were reported with a higher frequency (≥ 5 %) with Phesgo compared to intravenous pertuzumab in combination with trastuzumab: alopecia 79 % vs 73 %, myalgia 27.0 % vs 20.6 %, and dyspnea 12.1 % vs 6 %.

[…]

Table 2 Summary of ADRs in patients treated with pertuzumab, trastuzumab in pivotal clinical trials^,^^, and in the post-marketing setting†

	N = 3834^	N = 243^^	
	Pertuzumab+trastuzumab	Phesgo with chemotherapy	Phesgo monotherapy
ADR (MedDRA Preferred Term) System Organ Class	Frequency category	Frequency category	Frequency category
[…]			
Cardiac disorders			
Left ventricular dysfunction**	Common	Uncommon	Uncommon
Cardiac failure**	Common	Uncommon	Common

[…]

Description of selected adverse reactions
[…]

Febrile neutropenia

Phesgo ~~in combination with chemotherapy~~

In the pivotal trial FEDERICA, febrile neutropenia (Grade 3 or 4) occurred in 6.~~5~~6 % of Phesgo -treated patients and 5.6 % of intravenous pertuzumab and trastuzumab-treated patients during the neoadjuvant phase. No febrile neutropenia events (Grade 3 or 4) occurred during the adjuvant phase.

[…]

Immunogenicity

As with all therapeutic proteins, there is the potential for an immune response to pertuzumab and trastuzumab in patients treated with Phesgo.

In the FEDERICA study, the incidence of treatment-emergent anti-pertuzumab and anti-trastuzumab antibodies was ~~6.1~~10.6 % (26~~15~~/245) and 0.4 % (1/245), respectively, in patients treated with intravenous pertuzumab and trastuzumab. Among patients that tested positive to anti-pertuzumab antibodies, neutralizing anti-pertuzumab antibodies were detected in ~~two~~three patients.
~~The incidence of anti-pertuzumab and anti-trastuzumab antibodies detected at any time point (including baseline) was 10.3 % (26/252) and 1.2 % (3/252), respectively, in patients treated with intravenous pertuzumab and trastuzumab. Among these patients, neutralizing anti-pertuzumab antibodies were detected in three patients.~~

The incidence of treatment-emergent anti-pertuzumab, anti-trastuzumab, and anti-vorhyaluronidase alfa antibodies was ~~8.3~~12.9 % (31~~20~~/241), ~~1.7~~2.1 % (4~~5~~/241), and ~~3.8~~ 6.3 % (~~9~~15/238), respectively, in patients treated with Phesgo. Among these patients, neutralizing anti-pertuzumab antibodies were detected in two patients, and neutralizing anti-trastuzumab antibodies were detected in one patient.

~~The incidence of anti-pertuzumab, anti-trastuzumab, and anti-vorhyaluronidase alfa antibodies detected at any time point (including baseline) was 12.1 % (30/248), 3.2 % (8/248), and 9 % (22/245), respectively, in patients treated with Phesgo. Among these patients, neutralizing anti-pertuzumab antibodies were detected in three patients, neutralizing anti-trastuzumab antibodies were detected in one patient, and neutralizing anti-vorhyaluronidase alfa antibodies were detected in one patient.~~

The clinical relevance of the development of anti-pertuzumab, anti-trastuzumab or anti-vorhyaluronidase alfa antibodies after treatment with Phesgo is unknown.

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