אוקטובר 2021

Kadcyla®
קדסיילה
Trastuzumab Emtansine 20 mg/ml
Powder for concentrate for solution for infusion

רופא/ה יקר/ה, רוקח/ת יקר/ה,

חברת רוש פרמצבטיקה (ישראל) בע"מ מבקשת להודיעכם על עדכון בעלון לצרכן במתכונת עלון לרופא של התכשיר קדסיילה.
בהודעה זו מצוינים רק עדכונים מהותיים ועדכונים אשר מהווים החמרה.

ההתוויות הרשומות לתכשיר בישראל:

Early Breast Cancer (EBC)
KADCYLA, as a single agent, is indicated for the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab -based treatment.

Metastatic Breast Cancer (MBC)
Kadcyla, as a single agent, is indicated for the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination. Patients should have either:

- Received prior therapy for metastatic disease, or
- Developed disease recurrence during or within six months of completing adjuvant therapy.

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 שנשלח למשרד 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,

לילי אדר
רוקחת ממונה

בתאור צפרי-חגג
מחלקת רישום

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עדכונים מהותיים בעלון לרופא

בסעיף Posology and method of administration עודכן המידע הבא:

Posology

[…]
The initial dose should be administered as a 90 minute intravenous infusion. Patients should be observed during the infusion and for at least 90 minutes following the initial infusion for fever, chills, or other infusion-related reactions. The infusion site should be closely monitored for possible subcutaneous infiltration during administration. Cases of delayed epidermal injury or necrosis following extravasation have been observed in the post-marketing setting (see section 4.4 and 4.8).

Special populations

Elderly patients
No dose adjustment is required in patients aged ≥ 65 years. There are insufficient data to establish the safety and efficacy in patients ≥ 75 years due to limited data in this subgroup. However, for patients ≥65 years, subgroup analysis of 345 patients from study MO28231 shows a tendency of higher incidences of grade 3, 4 and 5 AE's, SAE's and AE's leading to drug discontinuation/interruption, but with a similar incidence of AEs of grade 3 and above classified as drug related.

בסעיף Special warnings and precautions for use עודכן המידע הבא:

[…]
Injection-site reactions
Extravasation of trastuzumab emtansine during intravenous injection may produce local pain**.** Exceptionally, cases of severe tissue lesions and epidermal necrosis may occur. If extravasation occurs, the infusion should be terminated immediately and the patient should be examined regularly as necrosis may occur within days to weeks after infusion.

בסעיף Undesirable effects עודכן המידע הבא:

[…]
Extravasation
Reactions secondary to extravasation have been observed in clinical studies with trastuzumab emtansine. These reactions were usually mild or moderate and comprised erythema, tenderness, skin irritation, pain, or swelling at the infusion site. These reactions have been observed more frequently within 24 hours of infusion. In the post-marketing setting, cases of epidermal injury or necrosis following extravasation have been exceptionally observed within days to weeks after infusion. Specific treatment for trastuzumab emtansine extravasation is unknown at this time (see section 4.4).