

נובמבר 2020

Kanjinti 150/420 (Trastuzumab)
Powder for concentrate for solution for infusion

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

אמג'ן אירופה בי.וי, בעלת הרישום, מבקשת להודיעך על עדכונים בעלון לרופא לתכשיר קיפרוליס. בהודעה זו מצוינים השינויים העיקריים בלבד.

ההתוויות המאושרות:

Metastatic breast cancer (MBC)

KANJINTI is indicated for the treatment of patients with metastatic breast cancer who have tumors 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)

KANJINTI 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.

KANJINTI 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)

KANJINTI 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 gastroesophageal junction who have not received prior anti-cancer treatment for their metastatic disease.

KANJINTI should only be used in patients with metastatic gastric cancer whose tumors have HER2 overexpression as defined by IHC 2+ and a confirmatory FISH+ result, or IHC 3+, as determined by an accurate and validated assay.

עדכונים מהותיים בעלון לרופא:

4.7 Effects on ability to drive and use machines

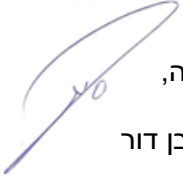
Trastuzumab ~~may have~~ a minor influence on the ability to drive or use machines (see section 4.8). Dizziness and somnolence may occur during treatment with trastuzumab (see section 4.8). Patients experiencing infusion-related symptoms (see section 4.4) should be advised not to drive and use machines until symptoms abate.

4.8 Undesirable effects

System organ class	Adverse reaction	Frequency
Infections and infestations	Infection	Very common
	Nasopharyngitis	Very common
	Neutropenic sepsis	Common
	Cystitis	Common
	Herpes-zoster	Common
	Influenza	Common
	Sinusitis	Common
	Skin infection	Common
	Rhinitis	Common
	Upper respiratory tract infection	Common
	Urinary tract infection	Common
	Erysipelas	Common
	Cellulitis	Common
	Pharyngitis	Common
	Sepsis	Uncommon
[...]		
Immune system disorders	Hypersensitivity	Common
	*Anaphylactic reaction	Rare/Not known
	+Anaphylactic shock	Rare/Not known
[...]		
Psychiatric disorders	Insomnia	Very common
	Anxiety	Common
	Depression	Common
	Thinking abnormal	Common
Nervous system disorders	¹ Tremor	Very common
	Dizziness	Very common
	Headache	Very common
	Paresthesia	Very common
	Dysgeusia	Very common
	Peripheral neuropathy	Common
	Hypertonia	Common
	Somnolence	Common
	Ataxia	Common
	Paresis	Rare
	Brain edema	Not known
[...]		
Cardiac disorders	¹ Blood pressure decreased	Very common
	¹ Blood pressure increased	Very common
	¹ Heart beat irregular	Very common
	⁴ Palpitation	Very common
	¹ Cardiac flutter	Very common
	Ejection fraction decreased*	Very common
	*Cardiac failure (congestive)	Common
	⁺¹ Supraventricular tachyarrhythmia	Common
	Cardiomyopathy	Common

System organ class	Adverse reaction	Frequency
	¹ Palpitation	Common
	Pericardial effusion	Uncommon
	Cardiogenic shock	Not known
	Pericarditis	Not known
	Bradycardia	Not known
	Gallop rhythm present	Not known
[...]		
Respiratory, thoracic and mediastinal disorders	⁺¹ Wheezing	Very common
	⁺ Dyspnea	Very common
	Cough	Very common
	Epistaxis	Very common
	Rhinorrhea	Very common
	⁺ Pneumonia	Common
	Asthma	Common
	Lung disorder	Common
	⁺ Pleural effusion	Common
	⁺¹ Wheezing	Uncommon
	Pneumonitis	UncommonRare
	⁺ Pulmonary fibrosis	Not known
	⁺ Respiratory distress	Not known
	⁺ Respiratory failure	Not known
	⁺ Lung infiltration	Not known
	⁺ Acute pulmonary edema	Not known
	⁺ Acute respiratory distress syndrome	Not known
	⁺ Bronchospasm	Not known
	⁺ Hypoxia	Not known
	⁺ Oxygen saturation decreased	Not known
	Laryngeal edema	Not known
	Orthopnea	Not known
	Pulmonary edema	Not known
	Interstitial lung disease	Not known
[...]		
Hepatobiliary disorders	Hepatocellular injury	Common
	Hepatitis	Common
	Liver tenderness	Common
	Jaundice	Rare
	Hepatic failure	Not known
[...]		

העלון לרופא המעודכן נשלח לפרסום במאגר התרופות שאתר משרד הבריאות, וניתן לקבלו גם על-ידי פניה למפיץ המקומי של התרופה, חברת מדיסון פארמה. שרות לקוחות: Medison-CS@medison.co.il טלפון: *5634

 בברכה,
סיגל בן דור
רוקחת ממונה