



# HERCEPTIN® (Trastuzumab) 600 mg/5ml

## S.C

### 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 הרספטיין 600 מ"ג/5 מ"ל S.C. בהודעה זו מצוינים רק עדכונים מהותיים ועדכונים אשר מהווים החמרה.

### ההתוויה הרשומה לתכשיר בישראל:

#### Metastatic breast cancer

Herceptin is indicated for the treatment of adult patients with HER2 positive metastatic breast cancer (MBC):

- as monotherapy for the treatment of those patients who have received at least two chemotherapy regimens for their metastatic disease. Prior chemotherapy must have included at least an anthracycline and a taxane unless patients are unsuitable for these treatments. Hormone receptor positive patients must also have failed hormonal therapy, unless patients are unsuitable for these treatments.
- in combination with paclitaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease and for whom an anthracycline is not suitable.
- in combination with docetaxel for the treatment of those patients who have not received chemotherapy for their metastatic disease.
- in combination with an aromatase inhibitor for the treatment of postmenopausal patients with hormone-receptor positive MBC, not previously treated with trastuzumab.

#### Early breast cancer

Herceptin is indicated for the treatment of adult patients with HER2 positive early breast cancer (EBC).

- following surgery, chemotherapy (neoadjuvant or adjuvant) and radiotherapy (if applicable).
- following adjuvant chemotherapy with doxorubicin and cyclophosphamide, in combination with paclitaxel or docetaxel.
- in combination with adjuvant chemotherapy consisting of docetaxel and carboplatin.
- in combination with neoadjuvant chemotherapy followed by adjuvant Herceptin therapy, for locally advanced (including inflammatory) disease or tumours > 2 cm in diameter.

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

### הסבר:

טקסט עם קו תחתו מציינ טקסט שהוסף לעלון.  
טקסט עם קו חוצה מציינ 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,



בתאור צפרי-חגג  
מחלקת רישום



לילי אדר  
רוקחת ממונה

## עדכונים מהותיים בעלון לרופא

בסעיף [4.7 Effects on ability to drive and use machines](#) עודכן המידע הבא:

Herceptin ~~may have~~ has a minor influence on the ability to drive or use machines (see section 4.8). Dizziness and somnolence may occur during treatment with Herceptin (see section 4.8). 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:

[...]

System organ class	Adverse reaction	Frequency
Infections and infestations	Infection	Very common
	Nasopharyngitis	Very common
	Neutropenic sepsis	Common
	Cystitis	Common
	<del>Herpes-zoster</del>	<del>Common</del>
	Influenza	Common
	Sinusitis	Common
	Skin infection	Common
	Rhinitis	Common
	Upper respiratory tract infection	Common
	Urinary tract infection	Common
	<del>Erysipelas</del>	<del>Common</del>
	<del>Cellulitis</del>	<del>Common</del>
	Pharyngitis	Common
Sepsis	Uncommon	
[...]		
Immune system disorders	Hypersensitivity	Common
	<sup>+</sup> Anaphylactic reaction	<del>Not known</del> <u>Rare</u>
	<sup>+</sup> Anaphylactic shock	<del>Not known</del> <u>Rare</u>
[...]		
Psychiatric disorders	Insomnia	Very common
	Anxiety	Common
	Depression	Common
	<del>Thinking abnormal</del>	<del>Common</del>
Nervous system disorders	<sup>1</sup> Tremor	Very common
	Dizziness	Very common
	Headache	Very common
	Paraesthesia	Very common
	Dysgeusia	Very common

<b>System organ class</b>	<b>Adverse reaction</b>	<b>Frequency</b>
	Peripheral neuropathy	Common
	Hypertonia	Common
	Somnolence	Common
	Ataxia	Common
	Paresis	Rare
	Brain oedema	Not known
[...]		
Cardiac disorders	<sup>1</sup> Blood pressure decreased	Very common
	<sup>1</sup> Blood pressure increased	Very common
	<sup>1</sup> Heart beat irregular	Very common
	<sup>+</sup> Palpitation	Very common
	<sup>1</sup> Cardiac flutter	Very common
	Ejection fraction decreased*	Very common
	<sup>+</sup> Cardiac failure (congestive)	Common
	<sup>+1</sup> Supraventricular tachyarrhythmia	Common
	Cardiomyopathy	Common
	<sup>1</sup> 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	<sup>++</sup> Wheezing	Very common
	<sup>+</sup> Dyspnoea	Very common
	Cough	Very common
	Epistaxis	Very common
	Rhinorrhoea	Very common
	<sup>+</sup> Pneumonia	Common
	Asthma	Common
	Lung disorder	Common
	<sup>+</sup> Pleural effusion	Common
	<sup>+1</sup> Wheezing	Uncommon
	Pneumonitis	Rare Uncommon
	<sup>+</sup> Pulmonary fibrosis	Not known
	<sup>+</sup> Respiratory distress	Not known
	<sup>+</sup> Respiratory failure	Not known
	<sup>+</sup> Lung infiltration	Not known
	<sup>+</sup> Acute pulmonary oedema	Not known
	<sup>+</sup> Acute respiratory distress syndrome	Not known
	<sup>+</sup> Bronchospasm	Not known
	<sup>+</sup> Hypoxia	Not known
	<sup>+</sup> Oxygen saturation decreased	Not known
	Laryngeal oedema	Not known
	Orthopnoea	Not known
	Pulmonary oedema	Not known
	Interstitial lung disease	Not known
[...]		
Hepatobiliary disorders	Hepatocellular Injury	Common
	Hepatitis	Common
	Liver Tenderness	Common
	Jaundice	Rare
	Hepatic Failure	Not known
[...]		

Herceptin subcutaneous formulation is a ready to use solution which should not be mixed or diluted with other products.

No incompatibilities between Herceptin subcutaneous formulation and polypropylene or polycarbonate syringe material or stainless steel transfer and injection needles and polyethylene Luer cone stoppers have been observed.