

אפריל 2021

רופא/ה נכבד/ה  
חוקח/ת נכבד/ה

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא של התכשיר:

## **CAELYX LIPOSOMAL 110-27-28836**

המאשר להתוויה:

First or second line therapy of aids related kaposi sarcoma in patients with low cd 4 counts and extensive mucocutaneous or visceral disease.

The treatment of patients with metastatic carcinoma of the ovary who are refractory to both paclitaxel and platinum-based chemotherapy regimens and who may also be refractory to topotecan. Refractory is defined as a patient having progressive disease while on treatment or within 6 months of completing treatment.

As monotherapy for patients with metastatic breast cancer where there is an increased cardiac risk.

In combination with bortezomib for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant.

השינויים המהותיים בעלון לרופא מופיעים בסעיפים הבאים:

### **4.8 Undesirable effects**

#### Summary of the safety profile

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Severe adverse reactions (Grade 3/4 adverse reactions occurring in  $\geq 2\%$  of patients) were neutropaenia, PPE, leukopaenia, lymphopaenia, anaemia, thrombocytopaenia, stomatitis, fatigue, diarrhoea, vomiting, nausea, pyrexia, dyspnoea, and pneumonia. Less frequently reported severe adverse reactions included Pneumocystis jirovecii pneumonia, abdominal pain, cytomegalovirus infection including cytomegalovirus chorioretinitis, asthenia, cardiac arrest, cardiac failure, cardiac failure congestive, pulmonary embolism, thrombophlebitis, venous thrombosis, anaphylactic reaction, anaphylactoid reaction, toxic epidermal necrolysis, and Stevens-Johnson syndrome.

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**Table 5: Adverse reactions in patients treated with Caelyx liposomal**

System Organ Class	Frequency All Grades	Adverse Drug Reaction
Infections and infestations	Common	Sepsis
		Pneumocystis jirovecii pneumonia
		Cytomegalovirus infection including cytomegalovirus chorioretinitis
		Mycobacterium avium complex infection
	Uncommon	Candidiasis
Rare	Fungal infection	
	Opportunistic infection (including Aspergillus, Histoplasma, Isospora, Legionella, Microsporidium, Salmonella, Staphylococcus, Toxoplasma, Tuberculosis) <sup>a</sup>	
Neoplasms benign, malignant and unspecified (including cysts and polyps)	Not known	Acute myeloid leukaemia <sup>b</sup>
		Myelodysplastic syndrome <sup>b</sup>
		Oral neoplasm <sup>b</sup>
Blood and lymphatic system disorders	Very common	Lymphopaenia
		Anaemia (including hypochromic)
	Uncommon	Pancytopenia
		Thrombocytosis
Rare	Bone marrow failure	

Immune system disorders	Uncommon	Anaphylactic reaction
	Rare	Anaphylactoid reaction
Metabolism and nutrition disorders	Very common	Decreased appetite
Psychiatric disorders	Common	Confusional state
Nervous system disorders	Uncommon	Polyneuropathy
		Convulsion
		Syncope
		Dysaesthesia
Eye disorders	Uncommon	Lacrimation increased
Cardiac disorders <sup>a</sup>	Common	Tachycardia
	Uncommon	Palpitations
		Cardiac arrest
		Cardiac failure
		Cardiac failure congestive
		Cardiomyopathy
		Cardiotoxicity
	Rare	Bundle branch block right
		Conduction disorder
		Atrioventricular block
Cyanosis		
Vascular disorders	Uncommon	Infusion site necrosis (including soft tissue necrosis and skin necrosis)
Respiratory, thoracic and mediastinal disorders	Uncommon	Asthma
		Chest discomfort
	Rare	Throat tightness
Gastrointestinal disorders	Common	Oesophagitis
	Rare	Lip ulceration
Skin and subcutaneous tissue disorders	Very common	Rash (including erythematous, maculo-papular, and papular)
	Common	Blister
	Uncommon	Dermatitis exfoliative
		Acne
		Skin ulcer
		Urticaria
		Skin discolouration
	Rare	Toxic epidermal necrolysis
		Erythema multiforme
		Dermatitis bullous
Not known	Stevens-Johnson syndrome <sup>b</sup>	
Musculoskeletal and connective tissue disorders	Very common	Musculoskeletal pain (including musculoskeletal chest pain, back pain, pain in extremity)
Reproductive disorders	Rare	Vaginal infection
General disorders and administration site conditions	Common	Mucosal inflammation
	Uncommon	Administration site extravasation
		Injection site reaction
Face oedema		
Investigations	Rare	Liver function test abnormal (including Blood bilirubin increased, Alanine aminotransferase increased and Aspartate aminotransferase increased)
Injury, poisoning and	Uncommon	Radiation recall phenomenon <sup>a</sup>

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procedural complications

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Radiation recall phenomenon

Recall of skin reaction due to prior radiotherapy has occurred uncommonly with Caelyx liposomal administration.

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כלל השינויים מסומנים בעלונים המצורפים כאשר הטקסט המודגש באדום הוסף לעלון ואילו הטקסט המחוק הוסר. בנוסף, הטקסט המודגש בסימון צהוב מסמן החמרה.

העלון לרופא והעלון לצרכן נשלחו לפרסום במלואם למאגר התרופות שבאתר משרד הבריאות. כמו כן, ניתן לקבלם מודפסים בפניה אלינו לטלפון 09-9591111.

להלן העדכונים.

בברכה,  
אלינה ורמן  
רוקחת ממונה