

ברצוננו להביא לידיעתכם את העדכון בעלון לרופא של התכשיר ביולי 2021:

Lipodox® Liposomal

הרכב וחוזק

doxorubicin hydrochloride 2mg/1 ml

התוויה כפי שאושרה בתעודת הרישום:

1. First or second line therapy of AIDS related Kaposi's sarcoma in patients with low CD 4 counts and extensive mucocutaneous or visceral disease.
2. 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.
3. As monotherapy for patients with metastatic breast cancer where there is an increased cardiac risk.
4. In combination with bortezomib for the treatment of progressive multiplemyeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant.

השינוי בעלון לרופא

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 Lipodox 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	
		Candidiasis	
	Uncommon	Fungal infection	
Rare	Opportunistic infection (including <i>Aspergillus</i> , <i>Histoplasma</i> , <i>Isospora</i> , <i>Legionella</i> , <i>Microsporidium</i> , <i>Salmonella</i> , <i>Staphylococcus</i> , <i>Toxoplasma</i> , <i>Tuberculosis</i>) ^a		
Neoplasms benign, malignant and unspecified (including cysts and polyps)	Not known	Acute myeloid leukaemia ^b	
		Myelodysplastic syndrome ^b	
		Oral neoplasm ^b	
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 ^a	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
	Rare	Chest discomfort Throat tightness
Gastrointestinal disorders	Common	Oesophagitis
	Rare	Lip ulceration
Skin and subcutaneous tissue disorders	Very common	Rash (including erythematous, maculopapular, 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 ^b	
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 procedural complications	Uncommon	Radiation recall phenomenon ^a

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Radiation recall phenomenon

Recall of skin reaction due to prior radiotherapy has occurred uncommonly with Lipodox Liposomal administration.

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העלון נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות
www.health.gov.il וניתן לקבלו מודפס על ידי פנייה לבעל הרישום:
 תרו אינטרנשיונל בע"מ, רחוב הקיטור 14, ת.ד. 10347 מפרץ חיפה 2624761
 ובטלפון 1-800-464664 .