

12-2024

חופא/ה נכבד/ה
רוקח/ת נכבד/ה

הנדון: דארזלקס 120 מ"ג/מ"ל תת עורי 1,800 מ"ג
Darzalex 120mg/ml S.C 1800mg

חברת J-C Health Care Ltd מבקשת להודיעכם כי העלון לרופא של התכשיר שבנדון התעדכן ב-12-2024.

פרטי העדכון העיקריים מופיעים בהמשך (טקסט שנוסף מסומן באדום, טקסט שהושמט מסומן בטקסט **בחול עם קו** **חוצה**, טקסט המהווה החמרה מודגש **ברקע צהוב**), אך קיימים עדכונים נוספים.

ההתוויות המאושרות לתכשיר בישראל:

- in combination with lenalidomide and dexamethasone or with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.
- in combination with bortezomib, thalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.
- in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.
- as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent and who have demonstrated disease progression on the last therapy.

מרכיב פעיל: Daratumumab

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:

<https://israel drugs.health.gov.il/#!/byDrug>

כמו כן, מצורפים לפרסום זה וניתן לקבל העתק מודפס שלהם באמצעות פנייה לבעל הרישום: J-C Health Care Ltd, קיבוץ שפיים, 6099000, טל': 09-9591111.

בברכה,

יעל לפידות מללי
רוקחת ממונה

J-C Health Care Ltd

העדכון בעלון לרופא הינו:

4.8 Undesirable effects

Table 5: Adverse reactions in multiple myeloma patients treated with intravenous daratumumab or subcutaneous daratumumab

System organ class	Adverse reaction	Frequency	Incidence (%)	
			Any grade	Grade 3-4
Infections and infestations	Upper respiratory tract infection ^a	Very common Very common	38 7 %	2%
	Bronchitis ^a	Very common	14%	2%
	Pneumonia ^a		14%	9%
	Urinary tract infection	Common	7%	1%
	Influenza	Common	4%	1% [#]
	Sepsis ^a	Common	4%	3%
	COVID-19^d		7	4
	Cytomegalovirus infection ^a	Common	1%	<1% [#]
	COVID-19^d	Common	7	4
Blood and lymphatic system disorders	Hepatitis B Virus reactivation ^a	Uncommon	<1%	<1%
	Neutropenia ^a	Very common	40%	33%
	Thrombocytopenia ^a	Very common	30%	18%
	Anaemia ^a	Very common	27%	12%
	Lymphopenia ^a	Very common	13%	11%
Immune system disorders	Leukopenia ^a	Very common	11%	6%
	Hypogammaglobulinemia ^a	Common	2	<1 [#]
Metabolism and nutrition disorders	Anaphylactic reaction ^b	Rare	-	-
	Decreased appetite	Very common	10%	1%
	Hyperglycaemia	Common	6%	3%
	Hypocalcaemia	Common	5%	1%
Psychiatric disorders	Dehydration	Common	2%	1% [#]
	Insomnia	Very common	14%	1% [#]
Nervous system disorders	Peripheral sensory neuropathy	Very common Very common	26%	3%
	Headache		11%	<1% [#]
	Dizziness	Common	9%	<1% [#]
	Paraesthesia	Common	9%	<1%
	Syncope	Common	3	2 [#]
Cardiac disorders	Atrial fibrillation	Common	3%	1%
Vascular disorders	Hypertension ^a	Very common	10 9 %	5%
Respiratory, thoracic and mediastinal disorders	Cough ^a	Very common	22%	<1% [#]
	Dyspnoea ^a	Very common	18%	2%
	Pulmonary oedema ^a	Common	1%	<1%
Gastrointestinal disorders	Diarrhoea	Very common	29%	3%
	Constipation	Very common	28%	1%
	Nausea	Very common	23%	1% [#]
	Vomiting	Very common	14%	1% [#]
	Pancreatitis ^a	Common	1%	<1%
Skin and subcutaneous	Rash	Common	9%	<1% [#]

tissue disorders	Pruritus	Common	5%	<1% [#]
Musculoskeletal and connective tissue disorders	Back pain	Very common	17%	2%
	Muscle spasms	Very common	12%	<1% [#]
	Arthralgia	Very common	10%	1% [#]
	Musculoskeletal chest pain	Common	6%	<1% [#]
General disorders and administration site conditions	Fatigue	Very common	23%	3%
	Oedema peripheral ^a	Very common	22%	1%
	Pyrexia	Very common	22%	1%
	Asthenia	Very common	18%	2%
	Chills	Common	9%	<1% [#]
	Injection site erythema ^c	Common	4%	0
	Injection site reactions ^{d,e}	Common	8%	0
Injury, poisoning and procedural complications	Infusion-related reactions ^c			
	Daratumumab intravenous ^f	Very common	39%	5%
	Daratumumab subcutaneous ^e	Very common	11%	1% [#]

[#] No grade 4

^a Indicates a grouping of terms.

^b Based on post-marketing adverse reactions.

^c Infusion-related reactions includes terms determined by investigators as related to infusion/injection of daratumumab.

^d Injection site reactions includes terms determined by investigators as related to injection of daratumumab.

^e Frequency based on daratumumab subcutaneous studies only (N=490).

^f Frequency based on daratumumab intravenous studies only (N=2324).

Note: Based on 2814 multiple myeloma patients treated with daratumumab intravenous or daratumumab subcutaneous.

^g Incidence is based on a subset of patients who received at least one dose of study treatment on or after 01 February 2020 (the start of the COVID-19 pandemic) from studies MMY3003, MMY3006, MMY3008 and MMY3013.

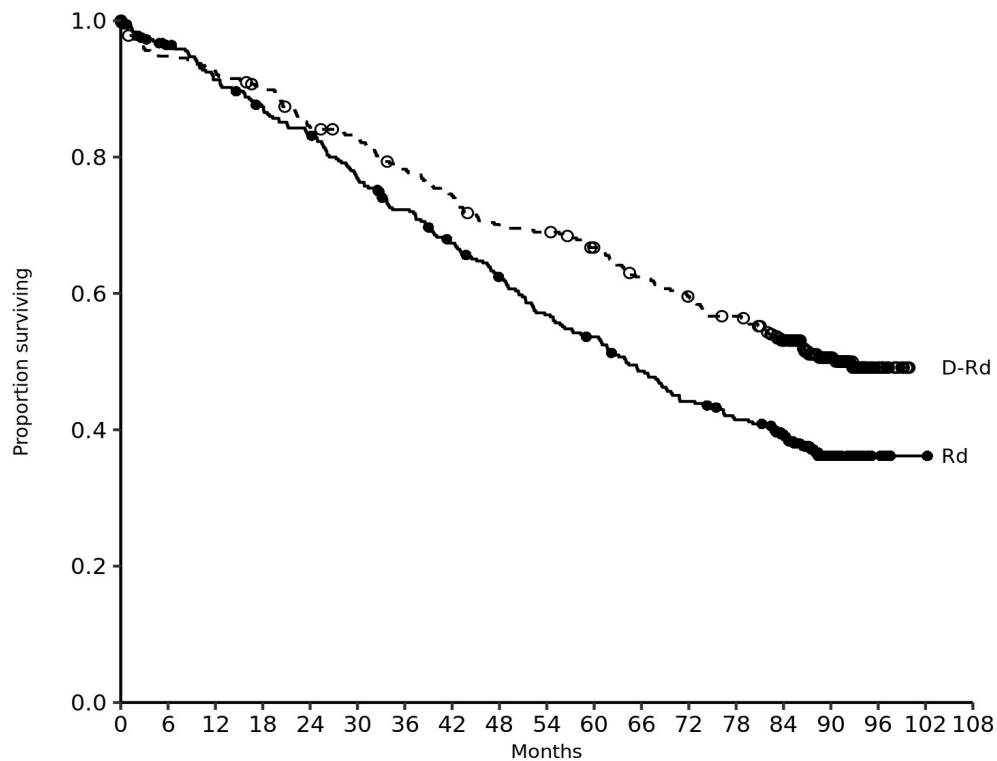
....

5.1 Pharmacodynamic properties

....

With a median follow-up of 56 months, DRd has shown an OS advantage over the Rd arm (HR=0.68; 95% CI: 0.53, 0.86; p=0.0013). Results of an updated OS analysis after a median of ~~64~~89 months continued to show an improvement in OS for patients in the DRd arm compared to the Rd arm. Median OS was ~~not reached~~90.3 months in the DRd arm and was ~~65.5~~64.1 months in the Rd arm (HR= ~~0.66~~0.67; 95% CI: ~~0.53~~0.55, ~~0.83~~0.82).

Figure 2 Kaplan-Meier curve of OS in study MMY3008



No. at risk

Rd	369	343	324	308	294	270	251	232	213	194	182	164	149	138	120	59	11	2	0
D-Rd	368	346	338	328	305	297	280	266	249	246	233	217	206	195	168	90	21	0	0

