

12-2024

רופא/ה נבד/ה
רוקחת נבד/ה

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

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

פרטי העדכון העיקריים מופיעים בהמשך (טקסט שנוסף מסומן באדום, טקסט שהושם מסומן בטקסט **בחול עטף כהה**, טקסט המהווה חומרה מודגש **ברקע צהוב**), אך קיימים עדכונים נוספים.

ההתווויות המאושרות לשיווק 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://israeldrugs.health.gov.il/#/byDrug>

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

בברכה,

יעל לפידות מליל
רוקחת ממונה
J-C Health Care Ltd

הערכה 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 <i>Very common</i>	38.7%	2%
	Bronchitis ^a	Very common	14%	2%
	Pneumonia ^a	Very common	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
	Hepatitis B Virus reactivation ^a	Uncommon	<1%	<1%
Blood and lymphatic system disorders	Neutropenia ^a	Very common	40%	33%
	Thrombocytopenia ^a	Very common	30%	18%
	Anaemia ^a	Very common	27%	12%
	Lymphopenia ^a	Very common	13%	11%
	Leukopenia ^a	Very common	11%	6%
Immune system disorders	Hypogammaglobulinemia ^a	Common	2	<1 [#]
	Anaphylactic reaction ^b	Rare	-	-
Metabolism and nutrition disorders	Decreased appetite	Very common	10%	1%
	Hyperglycaemia	Common	6%	3%
	Hypocalcaemia	Common	5%	1%
	Dehydration	Common	2%	1% [#]
Psychiatric disorders	Insomnia	Very common	14%	1% [#]
Nervous system disorders	Peripheral sensory neuropathy	Very common <i>Very common</i>	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	40.9%	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).

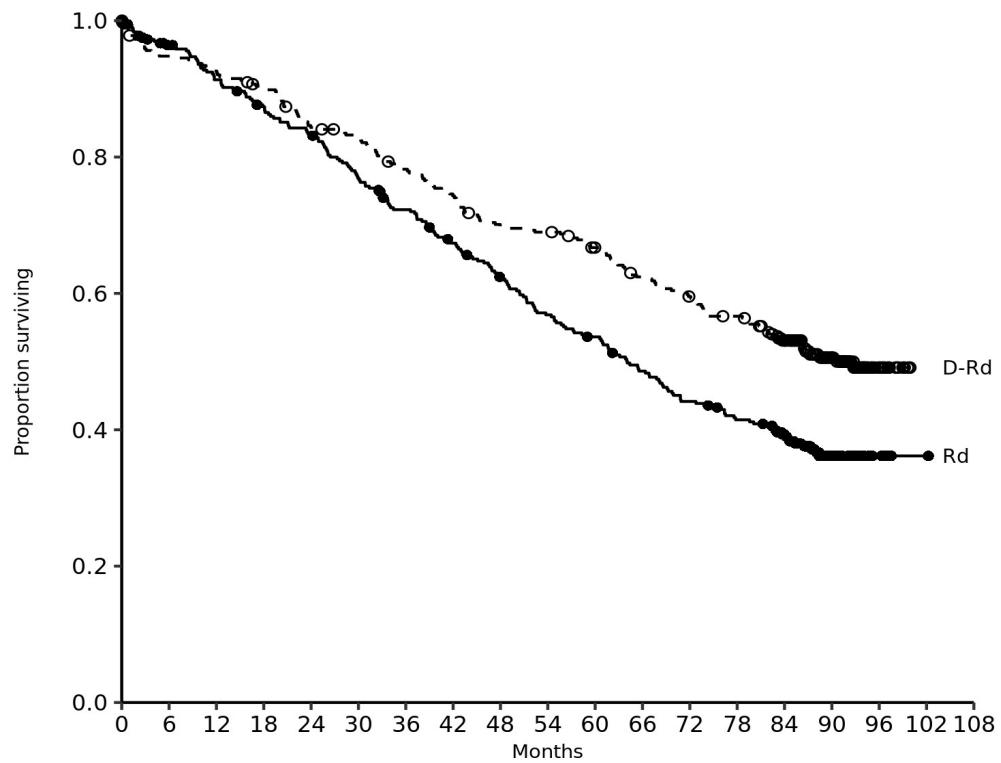
Note: Based on 2814 multiple myeloma patients treated with daratumumab intravenous or daratumumab subcutaneous.

^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 net reached 90.3 months in the DRd arm and was 65.564.1 months in the Rd arm (HR= 0.6667; 95% CI: 0.5355, 0.8382).

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

