

03-2025

רופא/ה נבבד/ה
רוקח/ת נבבד/ה

הנדון: DARZALEX 20 mg/mL I.V.
דארזלקס 20 מ"ג/מ"ל תוך ורידי

חברת J-C Health Care Ltd מבקשת להודיעכם כי העלון לרופא של התכשיר שבנדון התעדכן במרץ 2025.
פרטי העדכון העיקריים מופיעים בהמשך (טקסט שנוסף מסומן באדום, טקסט שהושמט מסומן בטקסט כחול 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

Posology

Dosing schedule in combination with lenalidomide and dexamethasone (4-week cycle regimen) and for monotherapy:

The recommended dose is [DARZALEX 20MG/ML I.V](#) DARZALEX 16 mg/kg body weight administered as an intravenous infusion according to the following dosing schedule in table 1.

Table 1: [DARZALEX 20MG/ML I.V](#) DARZALEX dosing schedule in combination with lenalidomide and dexamethasone (Rd) (4-week cycle dosing regimen) and monotherapy

Weeks	Schedule
Weeks 1 to 8	weekly (total of 8 doses)
Weeks 9 to 24 ^a	every two weeks (total of 8 doses)
Week 25 onwards until disease progression ^b	every four weeks

^a First dose of the every-2-week dosing schedule is given at week 9.

^b First dose of the every-4-week dosing schedule is given at week 25.

Dexamethasone should be administered at 40 mg/week (or a reduced dose of 20 mg/week for patients >75 years).

For dose and schedule of medicinal products administered with [DARZALEX 20MG/ML I.V](#) DARZALEX, see section 5.1 and the corresponding [prescribing information \(PI\)](#). [Summary of Product Characteristics](#).

Dosing schedule in combination with bortezomib, melphalan and prednisone (6-week cycle regimens):

The recommended dose is [DARZALEX 20MG/ML I.V](#) DARZALEX 16 mg/kg body weight administered as an intravenous infusion according to the following dosing schedule in table 2.

Table 2: [DARZALEX 20MG/ML I.V](#) DARZALEX dosing schedule in combination with bortezomib, melphalan and prednisone ([VMP]; 6-week cycle dosing regimen)

Weeks	Schedule
Weeks 1 to 6	weekly (total of 6 doses)
Weeks 7 to 54 ^a	every three weeks (total of 16 doses)
Week 55 onwards until disease progression ^b	every four weeks

^a First dose of the every-3-week dosing schedule is given at week 7.

^b First dose of the every-4-week dosing schedule is given at week 55.

Bortezomib is given twice weekly at weeks 1, 2, 4 and 5 for the first 6-week cycle, followed by **once** weekly at weeks 1, 2, 4 and 5 for eight more 6-week cycles. For information on the VMP dose and dosing schedule when administered with [DARZALEX 20MG/ML I.V](#) DARZALEX, see section 5.1.

Dosing schedule in combination with bortezomib, thalidomide and dexamethasone (4-week cycle regimens) for treatment of newly diagnosed patients eligible for autologous stem cell transplant (ASCT):

The recommended dose is [DARZALEX 20MG/ML I.V](#) DARZALEX 16 mg/kg body weight administered as an intravenous infusion according to the following dosing schedule in table 3.

Table 3: [DARZALEX 20MG/ML I.V](#) DARZALEX dosing schedule in combination with bortezomib, thalidomide and dexamethasone ([VTd]; 4-week cycle dosing regimen)

Treatment phase	Weeks	Schedule
Induction	Weeks 1 to 8	weekly (total of 8 doses)
	Weeks 9 to 16 ^a	every two weeks (total of 4 doses)
Stop for high dose chemotherapy and ASCT		

Consolidation	Weeks 1 to 8 ^b	every two weeks (total of 4 doses)
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- ^a First dose of the every-2-week dosing schedule is given at week 9.
^b First dose of the every-2-week dosing schedule is given at week 1 upon re-initiation of treatment following ASCT.

Dexamethasone should be administered at 40 mg on days 1, 2, 8, 9, 15, 16, 22 and 23 of cycles 1 and 2, and at 40 mg on days 1-2 and 20 mg on subsequent dosing days (days 8, 9, 15, 16) of cycles 3-4. Dexamethasone 20 mg should be administered on days 1, 2, 8, 9, 15, 16 in cycles 5 and 6.

For dose and schedule of medicinal products administered with [DARZALEX 20MG/ML I.V. DARZALEX](#), see section 5.1 and the corresponding [prescribing information \(PI\)](#). [Summary of Product Characteristics](#).

Dosing schedule in combination with bortezomib and dexamethasone (3-week cycle regimen):
 The recommended dose is [DARZALEX 20MG/ML I.V. DARZALEX](#) 16 mg/kg body weight administered as an intravenous infusion according to the following dosing schedule in table 4.

Table 4: [DARZALEX 20MG/ML I.V. DARZALEX](#) dosing schedule in combination with bortezomib and [dexamethasone \(Vd\)](#) (3-week cycle dosing regimen)

Weeks	Schedule
Weeks 1 to 9	weekly (total of 9 doses)
Weeks 10 to 24 ^a	every three weeks (total of 5 doses)
Week 25 onwards until disease progression ^b	every four weeks

- ^a First dose of the every-3-week dosing schedule is given at week 10.
^b First dose of the every-4-week dosing schedule is given at week 25.

Dexamethasone should be administered at 20 mg on days 1, 2, 4, 5, 8, 9, 11 and 12 of the first 8 bortezomib treatment cycles or a reduced dose of 20 mg/week for patients > 75 years, underweight (BMI <18.5), poorly controlled diabetes mellitus or prior intolerance to steroid therapy.

For dose and schedule of medicinal products administered with [DARZALEX 20MG/ML I.V. DARZALEX](#), see section 5.1 and the corresponding [prescribing information \(PI\)](#). [Summary of Product Characteristics](#).