J-C Health Care Ltd.
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03-2025

רופא/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 03-2025.

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:

Multiple myeloma
DARZALEX is indicated:

- 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.
- for the treatment of adult patients with multiple myeloma in combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (see section 5.1).
- 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.

Light chain (AL) amyloidosis
In combination with cyclophosphamide, bortezomib and dexamethasone for the treatment of adult patients with newly diagnosed systemic AL amyloidosis.

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 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

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העדכון בעלון לרופא הינו

3. PHARMACEUTICAL FORM

Solution for injection.
The solution is clear to opalescent, colourless to yellow.

~~Patient safety information card~~

~~The marketing of DARZALEX is subject to risk management plan (RMP) including a "patient safety information card". The "Patient safety information card" emphasizes important safety information that the patient should be aware of before and during treatment. Please explain to the patient the need to review the card before starting treatment.~~
The marketing of DARZALEX 20 MG/ML I.V is subject to risk management plan (RMP) including "Health Care Professional (HCP) Guide" and "patient safety information card".

HCP Guide
This product is marketed with prescriber guide providing important safety information. Please ensure you are familiar with this material as it contains important safety information.

Patient safety information card
The "Patient safety information card" emphasizes important safety information that the patient should be aware of before and during treatment. Please explain to the patient the need to review the card before starting treatment.

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4.2 Posology and method of administration

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Posology

Multiple myeloma

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

The recommended dose is 1800 mg of DARZALEX solution for subcutaneous injection administered over approximately 3-5 minutes according to the following dosing schedule in table 1.

Table 1: DARZALEX dosing schedule in combination with lenalidomide and dexamethasone (Rd), pomalidomide and dexamethasone (Pd) (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 solution for subcutaneous injection, see section 5.1 and the corresponding ~~Summary of Product Characteristics~~prescribing information (PI).

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

The recommended dose is 1800 mg of DARZALEX solution for subcutaneous injection administered over approximately 3-5 minutes according to the following dosing schedule in table 2.

Table 2: 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 solution for subcutaneous injection, 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 1800 mg of DARZALEX solution for subcutaneous injection administered over approximately 3-5 minutes according to the following dosing schedule in table 3.

Table 3: 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)

[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 solution for subcutaneous injection, 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 1800 mg of DARZALEX solution for subcutaneous injection administered over approximately 3-5 minutes according to the following dosing schedule in table 4.

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Table 4: 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 solution for subcutaneous injection, see section 5.1 and the corresponding prescribing information (PI).~~Summary of Product Characteristics.~~

AL amyloidosis
Dosing schedule in combination with bortezomib, cyclophosphamide and dexamethasone (4-week cycle regimens)
The recommended dose is 1800 mg of DARZALEX solution for subcutaneous injection administered over approximately 3-5 minutes according to the following dosing schedule in table 5.

Table 5: DARZALEX dosing schedule for AL amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone ([VCd];4-week cycle dosing regimen)[a]

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

[a] In the clinical study, DARZALEX was given until disease progression or a maximum of 24 cycles (~2 years) from the first dose of study treatment.
[b] First dose of the every-2-week dosing schedule is given at week 9
[c] First dose of the every-4-week dosing schedule is given at week 25

For dose and schedule of medicinal products administered with DARZALEX solution for subcutaneous injection, see section 5.1 and the corresponding prescribing information (PI)~~Summary of Product Characteristics~~.

Cardiac deficiency
No clinical data are available for patients with NYHA Class IIIB and IV since they were excluded from clinical trials. Very few data on patients with Mayo cardiac stage IIIB are available. No posology can be recommended (see section 5.1).

Missed dose
If a planned dose of DARZALEX is missed, the dose should be administered as soon as possible and the dosing schedule should be adjusted accordingly, maintaining the treatment interval.

Dose modifications
No dose reductions of DARZALEX are recommended. Dose delay may be required to allow recovery of blood cell counts in the event of haematological toxicity (see section 4.4). For information concerning medicinal products given in combination with DARZALEX, see corresponding prescribing information (PI).~~Summary of Product Characteristics.~~

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In clinical studies, no modification to rate or dose of DARZALEX solution for subcutaneous injection was required to manage IRRs.

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