

12-2025

חופא/ה נכבד/ה  
הוקח/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-12-2025.

פרטי העדכון העיקריים מופיעים בהמשך (טקסט שנוסף מסומן באדום, טקסט שהושמט מסומן בטקסט בחול עמ-קד-חצה, 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://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  
הוקחת ממונה  
J-C Health Care Ltd

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#### 4.2 Posology and method of administration

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##### Method of administration

DARZALEX subcutaneous formulation is not intended for intravenous administration and should be given by subcutaneous injection only, using the doses specified. **Use proper technique when withdrawing DARZALEX from the vial. To reduce the incidence of stopper coring, avoid the use of large diameter or blunt tip transfer needles or multiple stopper punctures.** See section 6.6 for special precautions prior to administration.

To avoid needle clogging, attach the hypodermic injection needle or subcutaneous infusion set to the syringe immediately prior to injection.

**Inject 15 mL DARZALEX solution for subcutaneous injection into the subcutaneous tissue of the abdomen approximately 7.5 cm to the right or left of the navel over approximately 3-5 minutes.** Do not inject DARZALEX solution for subcutaneous injection at other sites of the body as no data are available.

Injection sites should be rotated for successive injections.

DARZALEX solution for subcutaneous injection should never be injected into areas where the skin is red, bruised, tender, hard or areas where there are scars.

Pause or slow down delivery rate if the patient experiences pain. In the event pain is not alleviated by slowing down the injection, a second injection site may be chosen on the opposite side of the abdomen to deliver the remainder of the dose.

During treatment with DARZALEX solution for subcutaneous injection, do not administer other medicinal products for subcutaneous use at the same site as DARZALEX .

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#### 6.6 Special precautions for disposal and other handling

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##### Prepared syringe

Prepare the dosing syringe in controlled and validated aseptic conditions. **Withdraw 15 mL from the vial into a syringe using an 18G - 22G transfer needle with a regular bevel to minimise the risk of stopper coring. Insert the needle into the vial at a 90° angle within the ring of the stopper and minimise the number of punctures to prevent fragmentation of the stopper. Inspect the content of the syringe to ensure the absence of particulate matter, discolouration or other foreign particles.**

Once transferred from the vial into the syringe, store DARZALEX solution for subcutaneous injection for up to 24 hours refrigerated followed by up to 12 hours at 15 °C-25 °C and ambient light (see section 6.3). If stored in the refrigerator, allow the solution to reach ambient temperature before administration.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

The following information is intended for healthcare professionals only:

DARZALEX solution for subcutaneous injection should be administered by a healthcare professional.

To prevent medication errors, it is important to check the vial labels to ensure that the appropriate formulation (intravenous or subcutaneous formulation) and dose is being given to the patient as prescribed. DARZALEX solution for injection should be given by subcutaneous injection only, using the dose specified. DARZALEX subcutaneous formulation is not intended for intravenous administration.

DARZALEX solution for subcutaneous injection is for single use only and is ready to use.

- DARZALEX solution for subcutaneous injection is compatible with polypropylene or polyethylene syringe material; polypropylene, polyethylene, or polyvinyl chloride (PVC) subcutaneous infusion sets; and stainless steel transfer and injection needles.
- DARZALEX solution for subcutaneous injection should be a clear to opalescent and colourless to yellow solution. Do not use if opaque particles, discolouration or other foreign particles are present.
- Remove the DARZALEX solution for subcutaneous injection vial from refrigerated storage (2 °C – 8 °C) and equilibrate to ambient temperature (15 °C–30 °C). The unpunctured vial may be stored at ambient temperature and ambient light for a maximum of 24 hours in the original carton to protect from light. Keep out of direct sunlight. Do not shake.
- Prepare the dosing syringe in controlled and validated aseptic conditions. **Withdraw 15 mL from the vial into a syringe using an 18G - 22G transfer needle with a regular bevel to minimise the risk of stopper coring. Insert the needle into the vial at a 90° angle within the ring of the stopper and minimise the number of punctures to prevent fragmentation of the stopper. Inspect the content of the syringe to ensure the absence of particulate matter, discolouration or other foreign particles.**
- To avoid needle clogging, attach the hypodermic injection needle or subcutaneous infusion set to the syringe immediately prior to injection.

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