J-C Health Care Ltd.

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02-2023

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

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

חברת J-C Health Care Ltd מבקשת להודיעכם כי העלון לרופא של התכשיר שבנדון התעדכן ב <u>02-2023</u>.

פרטי העדכון <u>העיקריים</u> 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://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:

4.4 Special warnings and precautions for use

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Infusion-related reactions

DARZALEX 120MG/ML S.C. 1,800MG solution for subcutaneous injection can cause severe and/or serious IRRs, including anaphylactic reactions. In clinical studies, approximately 11% (52/490) of patients experienced an IRR. Most IRRs occurred following the first injection and were grade 1-2. IRRs occurring with subsequent injections were seen in less than 1% of patients (see section 4.8).

The median time to onset of IRRs following DARZALEX 120MG/ML S.C. 1,800MG injection was 3.7 hours (range 0.15-83 hours). The majority of IRRs occurred on the day of treatment. Delayed IRRs have occurred in ~~less than~~ 1% of patients.

Signs and symptoms of IRRs may include respiratory symptoms, such as nasal congestion, cough, throat irritation, allergic rhinitis, wheezing as well as pyrexia, chest pain, pruritis, chills, vomiting, nausea, ~~and~~ hypotension and blurred vision. Severe reactions have occurred, including bronchospasm, hypoxia, dyspnoea, hypertension ~~and~~ tachycardia and ocular adverse reactions (including choroidal effusion, acute myopia and acute angle closure glaucoma) (see section 4.8).

Patients should be pre-medicated with antihistamines, antipyretics, and corticosteroids as well as monitored and counselled regarding IRRs, especially during and following the first and second injections. If an anaphylactic reaction or life-threatening (grade 4) reactions occur, appropriate emergency care should be initiated immediately. DARZALEX 120MG/ML S.C. 1,800MG therapy should be discontinued immediately and permanently (see sections 4.2 and 4.3).

To reduce the risk of delayed IRRs, oral corticosteroids should be administered to all patients following DARZALEX 120MG/ML S.C. 1,800MG injection (see section 4.2). Patients with a history of chronic obstructive pulmonary disease may require additional post-injection medicinal products to manage respiratory complications. The use of post-injection medicinal products (e.g. short- and long-acting bronchodilators and inhaled corticosteroids) should be considered for patients with chronic obstructive pulmonary disease. If ocular symptoms occur, interrupt DARZALEX and seek immediate ophthalmologic evaluation prior to restarting DARZALEX (see section 4.2).

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4.8 Undesirable effects

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Description of selected adverse reactions

Infusion-related reactions (IRRs)
In clinical studies (monotherapy and combination treatments; N=490) with DARZALEX 120MG/ML S.C. 1,800MG subcutaneous formulation, the incidence of any grade IRRs was 10.2% with the first injection of DARZALEX 120MG/ML S.C. 1,800MG (1,800 mg, week 1), 0.2% with the week 2 injection, and 0.8% with subsequent injections. Grade 3 IRRs were seen in 1.4% of patients. No patients had grade 4 IRRs.

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