



אוגוסט 2023

פיזר פי אף אי פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, ישראל 46725
טל: 972-9-9700500 פקס: 972-9-9700501

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלון לרופא המשותף של התכשירים:

Solu Medrol 40mg

Solu Medrol 125mg

Solu Medrol 500mg

Solu Medrol 1000mg

המרכיב הפעיל:

Solu-Medrol 40 mg:

Methylprednisolone (as methylprednisolone sodium succinate) 40 mg/ Act-O-vial.

Solu-Medrol 125 mg:

Methylprednisolone (as methylprednisolone sodium succinate) 125 mg/ Act-O-vial.

Solu-Medrol 500 mg:

Methylprednisolone (as methylprednisolone sodium succinate) 500 mg/ Vial.

Solu-Medrol 1000 mg:

Methylprednisolone (as methylprednisolone sodium succinate) 1000 mg/ Vial.

Indicated for:

Solu Medrol is indicated to treat any condition in which IM or IV corticosteroid treatment is required such as: endocrine disorders, rheumatic disorders, collagen diseases, immune complex diseases, dermatologic diseases, allergic states, ophthalmic diseases, gastrointestinal diseases, respiratory diseases, hematologic disorders, management of neoplastic diseases, edematous states, nervous system disorders and organ transplantation.

להלן העדכונים העיקריים בעלון לרופא:

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4.4 Special warnings and precautions for use

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Other

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In post marketing experience tumour lysis syndrome (TLS) has been reported in patients with malignancies, including haematological malignancies and solid tumours, following the use of systemic corticosteroids alone or in combination with other chemotherapeutic agents. Patients at high risk of TLS, such as patients with tumours that have a high proliferative rate, high tumour burden and high sensitivity to cytotoxic agents, should be monitored closely and appropriate precautions should be taken.

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4.8 Undesirable effects

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MedDRA System Organ Class	Frequency	Undesirable Effects
<i>Endocrine disorders</i>	<i>Not Known</i>	Cushingoid; Hypothalamic pituitary adrenal axis suppression; Hypopituitarism Withdrawal symptoms - Too rapid a reduction of corticosteroid dosage following prolonged treatment can lead to acute adrenal insufficiency, hypotension and death. However, this is more applicable to corticosteroids with an indication where continuous therapy is given (see section 4.4). A 'withdrawal syndrome' may also occur including, fever, myalgia, arthralgia, rhinitis, conjunctivitis, painful itchy skin nodules and loss of weight.
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<i>Vascular disorders</i>	<i>Not Known</i>	Hypertension; Hypotension; Embolism arterial, Thrombotic events, Flushing
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6.4 Special precautions for storage

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SOLU-MEDROL® 40mg & 125 mg, After reconstitution with solvent:

Chemical and physical in-use stability of the reconstituted solution has been demonstrated for 12 hours , stored below 25°C .

From a microbiological point of view, unless the method of opening/ reconstitution/ dilution precludes the risk of microbial contamination, the product should be used immediately.

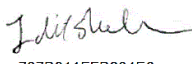
If not used immediately, in-use storage times and conditions are the responsibility of user.

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העלונים המעודכנים נשלחו למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות:
<https://israeldrugs.health.gov.il/#/byDrug>

לחילופין, לקבלת עלונים מלאים מודפסים ניתן לפנות לחברת פיזר פי אף אי פרמצבטיקה ישראל בע"מ
שנקר 9, ת.ד. 12133
הרצליה פיתוח, 46725.

בברכה,
עידית שלם אביר
רוקחת ממונה

DocuSigned by:

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