



אוקטובר 2024

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 השינויים הבאים עבור התכשיר **Solu Medrol 40mg**:

- שינוי בהרכב: החלפת לקטוז בסוכרוז

- שינוי בתנאי האחסון

- שינוי בצבע המכסה

כמו כן בהתאם לכך עודכן העלון 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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4.3 Contraindications

Solu-Medrol is contraindicated:

- in patients who have systemic fungal infections unless specific anti-infective therapy is employed and in cerebral oedema in malaria.
- in patients with known hypersensitivity to methylprednisolone or to any of the excipients listed in section 6.1.
- ~~Solu Medrol 40mg: in patients with a known or suspected allergy to cow's milk or its components, or other dairy products, because it contains trace amounts of milk ingredients (see section 4.4).~~
- for use by the intrathecal route of administration.

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4.4 Special warnings and precautions for use

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~~Cow's milk allergy—Solu Medrol 40mg/ml~~

Solu-Medrol 40mg/ml contains lactose monohydrate produced from bovine origin as an excipient and may therefore contain trace amounts of cow's milk proteins (the allergens of cow's milk). Serious allergic reactions, including bronchospasm and anaphylaxis, were reported in patients allergic to cow's milk proteins who were treated for acute allergic conditions. Patients with known or suspected allergy to cow's milk must not be administered Solu-Medrol 40mg/ml (see section 4.3).

Allergic reactions to cow's milk proteins should be considered in patients receiving Solu-Medrol 40mg/ml for the treatment of acute allergic conditions in whom symptoms worsen or who are presenting new allergic symptoms (see section 4.3). Administration of Solu-Medrol 40mg/ml should be stopped, and the patient's condition should be treated accordingly.

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6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Act-O-Vial System (Single Dose Vial)

SOLU-MEDROL® Sterile Powder 40 mg:

Each 1 ml Act-O-Vial contains:

I. Powder compartment: Sucrose, Dibasic sodium phosphate anhydrous, Monobasic sodium phosphate monohydrate, Sodium hydroxide, Water for injection

II. Diluent compartment: Water for injection

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6.4 Special precautions for storage

SOLU-MEDROL® 40mg ,

Store at or below 25°C.

After reconstitution with solvent:

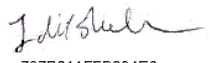
Store reconstituted solution below 25°C and use immediately OR store reconstituted solution at 2°C-8°C and use within 48 hours Store below 25°C.

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העלונים המעודכנים נשלחו למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות:
<https://israel drugs.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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