



פייזר פי אפי פרמצבטיקה ישראל בע"מ
רחוב שנקר 9, ת.ד. 12133
הרצליה פיתוח, ישראל 46725
טל: 972-9-9700501 פקס: 972-9-9700500

דצמבר 2018

רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא של התכשירים:

Solu Medrol 40mg /ml

Solu Medrol 125mg

Solu Medrol 500mg

Solu Medrol 1000mg

המרכיב הפעיל:

Solu-Medrol 40 mg: Methylprednisolone (as methylprednisolone sodium succinate) 40 mg.

Solu-Medrol 125 mg: Methylprednisolone (as methylprednisolone sodium succinate) 125 mg.

Solu-Medrol 500 mg: Methylprednisolone (as methylprednisolone sodium succinate) 500 mg.

Solu-Medrol 1000 mg: Methylprednisolone (as methylprednisolone sodium succinate) 1000 mg.

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 העדכנים העיקריים בעלון לרופא:

4.4 Special warnings and precautions for use

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Ocular Effects

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. Central serous chorioretinopathy, may lead to retinal detachment.

Frequent patient monitoring is necessary in patients with glaucoma (or a family history of glaucoma) and in patients with ocular herpes simplex, for fear of corneal perforation.

Prolonged use of corticosteroids may produce posterior subcapsular cataracts and nuclear cataracts (particularly in children), exophthalmos, or increased intraocular pressure, which may result in glaucoma with possible damage to the optic nerves. Establishment of secondary fungal and viral infections of the eye may also be enhanced in patients receiving glucocorticoids.

Corticosteroid therapy has been associated with chorioretinopathy, which may lead to retinal detachment.

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4.8 Undesirable effects

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<i>Eye disorders</i>	<i>Rare</i>	Vision blurred (see also section 4.4).
	<i>Not Known</i>	Posterior subcapsular cataracts; Exophthalmos; Glaucoma; Papilloedema with possible damage to the optic nerve; Corneal or scleral thinning; Exacerbation of ophthalmic viral or fungal disease; Chorioretinopathy.

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השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמתת מידע ועודכו נסח שאינו מהווים החמרה.

העלונים המעודכנים נשלחו למשרד הבריאות לצורך פרסום במאגר התרופות שבאתר משרד הבריאות:
<https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h>

חולופין, קיבלת עלונים מלאים מודפסים ניתן לפנות לחברת פיזר פי אפי פרמצטטיקה ישראל בע"מ
 שנקר 9, ת.ד. 12133 הרצליה פיתוח, 46725.

בברכה,
 אורטל עבדי
 רוקחת ממונה