פייזר 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

דצמבר 2018

רופא/ה, רוקח/ת נכבד/ה,

חב' פייזר פי אף אי מבקשת להודיע על עדכון בעלונים לרופא ולצרכן של התכשיר **DEPO MEDROL**

המרכיב הפעיל בתכשיר:

METHYLPREDNISOLONE ACETATE 40 mg/ mL

התוויה רשומה:

Indicated for:
For the treatment of conditions responsive to steroid injection therapy.

להלן העדכונים העיקריים בעלון לרופא:

4.2 Posology and Method of Administration

....

B. IN SITU ADMINISTRATION FOR LOCAL EFFECT

1. Rheumatoid and osteoarthritis

The dose for intra-articular administration depends upon the size of the joint and varies with the severity of the condition in the individual patient. In chronic cases, **repeated injections, if needed, may be given at intervals of one to five or more weeks** ~~several injections can vary from one to five per week~~, depending on the degree of relief obtained from the initial injection.

....

4.4 Special warnings and precautions for use

....

Gastrointestinal Effects

....

There is no universal agreement on whether corticosteroids per se are responsible for peptic ulcers encountered during therapy; however, glucocorticoid therapy may mask the symptoms of peptic ulcer so that perforation or haemorrhage may occur without significant pain. Glucocorticoid therapy may mask peritonitis or other signs or symptoms associated with gastrointestinal disorders such as perforation, obstruction or pancreatitis. In combination with NSAIDs, the risk of developing gastrointestinal ulcers is increased.

....

Renal and Urinary Disorders

Caution is required in patients with systemic sclerosis because an increased incidence of scleroderma renal crisis has been observed with corticosteroids, including methylprednisolone. Blood pressure and renal function (s-creatinine) should therefore be routinely checked. When renal crisis is suspected, blood pressure should be carefully controlled.

....

Other

Corticosteroids should be used with caution in patients with a predisposition to thrombophlebitis.

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects (see section 4.5).

....

4.5 Interaction with other medicinal products and other forms of interaction

....

9. Antivirals - HIV protease inhibitors:
1) Indinavir ritonavir and pharmacokinetic enhancers (cobicistat) (CYP3A4 inhibitors and substrates) may increase plasma concentrations of corticosteroids.

....

4.6 Fertility, pregnancy and lactation

Fertility

Corticosteroids have been shown to impair fertility in animal studies

~~There is no evidence that corticosteroids impair fertility~~

....

Pregnancy

....

In humans, the risk of low birth weight appears to be dose related and may be minimized by administering lower corticosteroid doses.

However, corticosteroids do not appear to cause congenital anomalies when given to pregnant women.

....

Since adequate human reproductive studies have not been done with methylprednisolone acetate, this medicinal product should be used during pregnancy only after a careful assessment of the benefit-risk ratio to the mother and fetus.

....

Breast-feeding

This medicinal product should be used during breast feeding only after a careful assessment of the benefit-risk ratio to the mother and infant.

....

4.8 Undesirable effects

MedDRA System Organ Class	**Frequency**	**Undesirable Effects**
Immune system disorders	***Not Known***	Drug hypersensitivity, Anaphylactic reaction, Anaphylactoid reaction
Nervous system disorders	***Not Known***	Intracranial pressure increased (with Papilloedema [Benign intracranial hypertension]); Seizure ~~Convulsion;~~ Amnesia; Cognitive disorder; Dizziness; Headache;
Skin and subcutaneous tissue disorders	***Not Known***	~~Ecchymosis; Acne;~~ Angioedema; Hirsutism; Petechiae; Ecchymosis; Skin atrophy; Erythema; Hyperhidrosis; Skin striae; Skin hyperpigmentation; Rash; Pruritus; Urticaria; Acne; Skin hypopigmentation; ~~Hirsutism; Rash; Erythema; Pruritus; Urticaria; Hyperhidrosis~~
General disorders and administration site conditions	***Not Known***	Abscess sterile; Impaired healing; Oedema peripheral; Fatigue; Malaise; ~~Irritability (in children)~~; Injection site reaction; ~~Abscess sterile; Fatigue; Malaise; Irritability (in adults)~~
Investigations	***Not Known***	Blood potassium decreased; Alanine aminotransferase increased; Aspartate aminotransferase increased; Blood alkaline phosphatase increased; Carbohydrate tolerance decreased; Urine calcium increased; suppression of reactions to skin tests [not a MedDRA PT]; Blood urea increased; ~~Nitrogen balance negative (due to protein catabolism)~~

† Common (≥1/100 to <1/10); Uncommon (≥1/1,000 to <1/100); Rare (≥1/10,000 to <1/1,000); Not known (frequency cannot be estimated from the available data)

#Peritonitis may be the primary presenting sign or symptom of a gastrointestinal disorder such as perforation, obstruction or pancreatitis .

CERTAIN SIDE EFFECTS REPORTED WITH SOME CONTRAINDICATED AND NON-RECOMMENDED ROUTES OF ADMINISTRATION.

Intrathecal/Epidural: Usual systemic corticoid adverse reactions, headache, meningismus, meningitis, paraparesis/paraplegia, spinal fluid abnormalities, nausea, vomiting, sweating, arachnoiditis, functional gastrointestinal disorder/bladder dysfunction, Seizure ~~convulsions~~, sensory disturbance. ~~The frequency of these adverse reactions is not known.~~

....

5.3 Preclinical safety data

....

Reproductive toxicity:

Corticosteroids have been shown to reduce fertility when administered to rats. Male rats were administered corticosterone at doses of 0, 10, and 25 mg/kg/day by subcutaneous injection once daily for 6 weeks and mated with untreated females. The high dose was reduced to 20 mg/kg/day after Day 15. Decreased copulatory plugs were observed, which may have been secondary to decreased accessory organ weight. The numbers of implantations and live fetuses were reduced.

....

השינויים המודגשים בצהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע (טקסט מחוק מסומן בקו חוצה) ועדכוני נוסח שאינם מהווים החמרה.

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

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

בברכה,
עידית שלם-אבידר
רוקחת ממונה