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

יולי 2021

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.

<u>להלן העדכונים העיקריים בעלון לרופא:</u>

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4.4 Special warnings and precautions for use

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Other

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Depo-Medrol contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

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<u>להלן העדכונים העיקריים בעלון לצרכן:</u>

2. <u>לפני השימוש בתרופה</u>

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מידע חשוב על חלק מהמרכיבים של התרופה

דפו מדרול™ 40 מ"ג/מ"ל מכילה פחות מ-1 מילימול (23 מ"ג) נתרן בבקבוקון, ניתן לומר שהיא בעיקרון "נטולת נתרן"

3. <u>כיצד תשתמש בתרופה?</u>

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מבוגרים

מינונים מומלצים:

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דלקת אמתחת (בורסיטיס), דלקת גיד (טנדיניטיס) ואפיקונדיליטיס (epicondylitis):

המנה הרגילה היא בין 4-30 מ"ג (0.1-0.75 מ"ל). ברוב המקרים לא ידרשו זריקות חוזרות לדלקת אמתחת (בורסיטיס) ואפיקונדיליטיס (epicondylitis). יתכן שידרשו זריקות חוזרות לטיפול במצבים ממושכים.

מצבים רפואיים עוריים:

המנה הרגילה היא בין 20-60 מ"ג (0.5-1.5 מ"ל), בהזרקה לאזור או האזורים הנגועים של העור.

מצבים רפואיים אחרים:

למצבים אחרים כלליים יותר,ייתכן שתידרש מנה של 40-120 מ"ג (1-3 מ"ל) מתרופה זו בחוקן לרקטום או בהזרקה לתוך שריר גדול.

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<u>הוספת הוראות לצוות הרפואי:</u>

The following information is intended for healthcare professionals only:

FOR FURTHER INFORMATION PLEASE REFER TO THE PHYSICIAN LEAFLET.

Posology and method of administration

Depo-Medrol should not be mixed with any other suspending agent or solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to

administration, whenever suspension and container permit. Depo-Medrol may be used by any of the following routes: intramuscular, intra-articular, periarticular, intrabursal, intralesional in intrarectal instillation and into the soft tissues. It must not be used by the intrathecal or intravenous routes. Undesirable effects may be minimized by using the lowest effective dose for the minimum period (see special warnings and precautions).
Depo-Medrol vials are intended for single dose use only.
Adults
Intramuscular – for sustained systemic effect: Allergic conditions (asthma). 80 – 120 mg (2 – 3 ml). Dermatological conditions, 80 – 120 mg (1 – 3 ml).
Rheumatic disorders and collagen diseases (rheumatoid arthritis), 40 – 120 mg (1 – 3 ml) per week. Dosage must be individualised and depends on the condition being treated and its severity.
The frequency of intramuscular injections should be determined by the duration of the clinical response.
On average the effect of a single 2 ml (80 mg) injection may be expected to last approximately two weeks.
Intra-articular: Rheumatoid arthritis, osteo-arthritis. The dose of Depo-Medrol depends upon the size of the joint and the severity of the condition. Repeated injections, if needed, may be given at intervals of one to five or more weeks depending upon the degree of relief obtained from the initial injection. A suggested dosage guide is: large joint (knee, ankle, shoulder), 20 – 80 mg (0.5 – 2 ml); medium joint (elbow, wrist), 10 – 40 mg (0.25 – 1 ml); small joint (metacarpophalangeal, interphalangeal, sternoclavicular, acromioclavicular), 4 – 10 mg (0.1 – 0.25 ml).
Intrabursal: Subdeltoid bursitis, prepatellar bursitis, olecranon bursitis. For administration directly into bursae, 4 – 30 mg (0.1 – 0.75 ml). In most cases, repeat injections are not needed.
Intralesional: For administration directly into the lesion for local effect in dermatological conditions, 20 – 60 mg (0.5 – 1.5 ml). For large lesions, the dose may be distributed by repeated local injections of 20 – 40 mg (0.5 – 1 ml). One to four injections are usually employed. Care should be taken to avoid injection of sufficient material to cause blanching, since this may be followed by a small slough.
Periarticular: Epicondylitis. Infiltrate 4 – 30 mg (0.1 – 0.75 ml) into the affected area.
Into the tendon sheath: Tenosynovitis, epicondylitis. For administration directly into the tendon sheath, 4 – 30 mg (0.1 – 0.75 ml). In recurrent or chronic conditions, repeat injections may be necessary.
Special precautions should be observed when administering Depo-Medrol. Intramuscular injections should be made deeply into the gluteal muscles. The usual technique of aspirating prior to injection should be employed to avoid intravascular administration. Doses recommended for intramuscular injection must not be administered superficially or subcutaneously.
Intra-articular injections should be made using precise, anatomical localisation into the synovial space of the joint involved. The injection site for each joint is determined by that location where the synovial cavity is most superficial and most free of large vessels and nerves. Suitable sites for intra-articular injection are the knee, ankle, wrist, elbow, shoulder, phalangeal and hip joints. The spinal joints, unstable joints and those devoid of synovial space are not suitable. Treatment failures age most frequently the result of failure to enter the joint space. Intra-articular injections should be made with care as follows: ensure correct positioning of the needle into the synovial space and aspirate a few drops of joint fluid. The aspirating syringe should then be replaced by another containing Depo-Medrol. To ensure position of the needle, synovial fluid should be aspirated and the injection made. After injection the joint is moved slightly to aid mixing of the synovial fluid and the suspension. Subsequent to therapy care should be taken for the patient not to overuse the joint in which benefit has been obtained. Negligence in this matter may permit an increase in joint deterioration that will more than offset the beneficial effects of the steroid.
Intrabursal injections should be made as follows: the area around the injection site is prepared in a sterile way and a wheal at the site made with 1 per cent procaine hydrochloride solution. A 20-24 gauge needle attached to a dry syringe is inserted into the bursa and the fluid aspirated. The needle is left in place and the aspirating syringe changed for a small syringe containing the desired dose. After injection, the needle is withdrawn and a small dressing applied. In the treatment of tenosynovitis care should be taken to inject Depo-Medrol into the tendon sheath rather than into the

substance of the tendon. Due to the absence of a true tendon sheath, the Achilles tendon should not be injected with Depo-Medrol.
The usual sterile precautions should be observed with each injection.
Paediatric population
Dosage may be reduced for infants and children but should be governed more by the severity of the condition and response of the patient, than by age or size.
Elderly patients
When used according to instructions, there is no information to suggest that a change in dosage is warranted in the elderly. However, treatment of elderly patients, particularly if long-term, should be planned bearing in mind the more serious consequences of the common side-effects of corticosteroids in old age and close clinical supervision is required.

- **Incompatibilities**

None stated.

Special precautions for disposal and other handling

Do not freeze. Depo-Medrol should not be mixed with any other fluid.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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

העלונים המעודכנים 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