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

אוקטובר 2021

רופא/ה, רוקח/ת נכבד/ה,

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

המרכיבים הפעילים בתכשיר:

METHYLPREDNISOLONE ACETATE 40 mg/ mL
LIDOCAINE (AS HYDROCHLORIDE) 10 mg/ mL

התוויות רשומות:

Depo-Medrol with Lidocaine is indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:
- synovitis of osteoarthritis
- rheumatoid arthritis
- acute and subacute bursitis
- acute gouty arthritis
- epicondylitis
- acute nonspecific tenosynovitis
- post-traumatic osteoarthritis

להלן העדכונים העיקריים בעלון לרופא:

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4.6 Fertility, pregnancy and lactation

Fertility

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Corticosteroids have been shown to impair fertility in animal studies

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5.3 Preclinical safety data

Methylprednisolone

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Mutagenesis:

Methylprednisolone has not been formally evaluated for genotoxicity. Studies using structurally related analogues of methylprednisolone showed no evidence of a potential for genetic and chromosome mutations in limited studies in bacteria and mammalian cells.

Methylprednisolone has not been formally evaluated in rodent carcinogenicity studies. Variable results have been obtained with other glucocorticoids tested for carcinogenicity in mice and rats. However, published data indicate that several related glucocorticoids including budesonide, prednisolone, and triamcinolone acetonide can increase the incidence of hepatocellular adenomas and carcinomas after oral administration in drinking water to male rats. These tumorigenic effects occurred at doses which were less than the typical clinical doses on a mg/m^2 basis. The clinical relevance of these findings is unknown.

Reproductive toxicity:

Methylprednisolone has not been evaluated in animal fertility studies. Corticosteroids have been shown to reduce fertility when administered to rats. Adverse effects on fertility in male rats administered corticosterone were observed and were reversible. Decreased weights and microscopic changes in prostate and seminal vesicles were observed. The numbers of implantations and live foetuses were reduced and these effects were not present following mating at the end of the recovery period.

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Lidocaine

Carcinogenesis:

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of lidocaine. A metabolite of lidocaine, 2,6-xylidine, has been shown to be carcinogenic in rats with unknown clinical relevance in relation to short-term/intermittent use of lidocaine as a local anaesthetic.

Mutagenesis:

Genotoxicity tests with lidocaine showed no evidence of mutagenic potential. A metabolite of lidocaine, 2,6-xylidine, showed weak genotoxic potential in vitro and in vivo.

Reproductive toxicity:
A study was conducted on male and female rats administered orally 30 mg/kg bw of lidocaine daily for 8 months. During that period, 3 matings were conducted and reproductive parameters were analysed for each gestation, as well as offspring development up to weaning. No effects could be detected.

להלן העדכונים העיקריים בעלון לצרכן:

1. למה מיועדת התרופה?

לטיפול משלים קצר טווח (במהלך חריף או החמרה) במצבים הבאים:
- דלקת קרום סינובי (סינוביטיס) או דלקת מפרקים ניוונית (אוסטאוארתריטיס)
- דלקת מפרקים שגרונית (ראומטואידית)
- דלקת אמתחת (בורסיטיס) אקוטית ותת-אקוטית
- דלקת מפרקים שיגדונית חריפה (gouty arthritis)
- אפיקונדיליטיס (epicondylitis)
- טנוסינוביטיס חריף שאינו ספציפי
- אוסטאוארתריטיס פוסט-טראומטי

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4. תופעות לוואי

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- **זיהומים**, התרופה יכולה להסתיר או לשנות את הסימנים והתסמינים של זיהומים מסוימים, או להפחית את התנגודת לזיהום, מה שמקשה על אבחונם בשלב מוקדם. התסמינים יכולים לכלול עלייה בחום והרגשה לא טובה. תסמינים של התפרצות חוזרת של זיהום שחפת שהיה בעבר יכולים להיות שיעול דמי או כאב בחזה. בנוסף, התרופה עלולה לגרום לך לפתח זיהום חמור בסבירות גבוהה יותר.

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הוספת הוראות לצוות הרפואי:

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® with Lidocaine should not be mixed with any other preparation as flocculation of the product may occur. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever suspension and container permit. Depo- Medrol® with Lidocaine may be used by any of the following routes: intra-articular, intrabursal, intrasynovial and into the cyst and tendon sheath. It must not be used by the intrathecal, or intravenous routes.
Adults
Intra-articular: Rheumatoid arthritis, osteo-arthritis. The dose of Depo- Medrol® with Lidocaine depends on 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), 0.5 - 2 ml (20 - 80 mg of steroid); medium joint (elbow, wrist), 0.25 - 1 ml (10 - 40 mg of steroid); small joint (metacarpophalangeal, interphalangeal, sternoclavicular, acromioclavicular), 0.1 - 0.25 ml (4 - 10 mg of steroid).
Intrabursal: Subdeltoid bursitis, prepatellar bursitis, olecranon bursitis. For administration directly into bursae, 0.1 - 0.75 ml (4 - 30 mg of steroid). In most acute cases, repeat injections are not needed.
Into the tendon sheath: Tendinitis, tenosynovitis, epicondylitis. For administration directly into the tendon sheath, 0.1 - 0.75 ml (4 - 30 mg of steroid). In recurrent or chronic conditions, repeat injections may be necessary.

Paediatric population
For infants and children, the recommended dosage should be reduced, but dosage should be governed by the severity of the condition rather than by strict adherence to the ratio indicated by age or body weight.
Elderly
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.
Special precautions should be observed when administering Depo- Medrol® with Lidocaine:
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 are 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® with Lidocaine. 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 percent procaine hydrochloride solution. A 20 to 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 and tendinitis, care should be taken to inject Depo- Medrol® with Lidocaine 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® with Lidocaine.
The usual sterile precautions should be observed with each injection.

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Special precautions for storage

Store below 25°C.
Do not freeze.

Special precautions for disposal and other handling

No special requirements for disposal.
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
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הרצליה פיתוח, 46725.

בברכה,
עידית שלם-אבידר
רוקחת ממונה