



פיזר פי אף אי פרמצבטיקה ישראל בע"מ
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אוגוסט 2024

רופא/ה, רוקח/ת נכבד/ה,

חב' פיזר PFE מבקשת להודיע על עדכון בעלונים לרופא של התכשירים:

SOLU CORTEF 100mg , POWDER FOR SOLUTION FOR INJECTION/ INFUSION

הרכב וחוזק:

Hydrocortisone (as sodium succinate) 100mg

SOLU CORTEF 500MG, POWDER FOR SOLUTION FOR INJECTION/ INFUSION

הרכב וחוזק :

Hydrocortisone (as sodium succinate) 500mg/ Vial

התוויה:

Solu-Cortef is indicated to treat any condition in which IM or IV corticosteroid treatment is required such as: allergic states, dermatologic diseases, endocrine disorders, gastrointestinal diseases, hematologic disorders, neoplastic diseases, nervous system disorders, ophthalmic diseases, renal diseases, respiratory diseases, rheumatic disorders, certain medical emergencies.

להלן העדכון העיקרי בעלונים לרופא:

WARNINGS

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Cardio-renal:

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There have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and congestive heart failure (see CONTRAINDICATIONS and PRECAUTIONS: Drug Interactions, Amphotericin B injection and potassium-depleting agents).

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Immunosuppression and Increased Risk of Infection

Corticosteroids, including SOLU-CORTEF, suppress the immune system and increase the risk of infection with any pathogen, including viral, bacterial, fungal, protozoan, or helminthic pathogens. Corticosteroids can:

- Reduce resistance to new infections
- Exacerbate existing infections
- Increase the risk of disseminated infections
- Increase the risk of reactivation or exacerbation of latent infections
- Mask some signs of infection

Corticosteroid-associated infections can be mild but can be severe and at times fatal. The rate of infectious complications increases with increasing corticosteroid dosages.

Monitor for the development of infection and consider SOLU-CORTEF withdrawal or dosage reduction as needed. Do not administer SOLU-CORTEF by an intraarticular, intrabursal, or intratendinous route in the presence of acute local infection.

Tuberculosis

If SOLU-CORTEF is used to treat a condition in patients with latent tuberculosis or tuberculin reactivity, reactivation of the disease may occur. Closely monitor such patients for reactivation.

.During prolonged SOLU-CORTEF therapy, patients with latent tuberculosis or tuberculin reactivity should receive chemoprophylaxis.

Varicella Zoster and Measles Viral Infections

Varicella and measles can have a serious or even fatal course in non-immune patients taking corticosteroids. In corticosteroid-treated patients who have not had these diseases or are nonimmune,

particular care should be taken to avoid exposure to varicella and measles:

- If a SOLU-CORTEF-treated patient is exposed to varicella, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If varicella develops, treatment with antiviral agents may be considered.
- If a SOLU-CORTEF-treated patient is exposed to measles, prophylaxis with immunoglobulin (IG) may be indicated.

Hepatitis B Virus Reactivation

Hepatitis B virus reactivation can occur in patients who are hepatitis B carriers treated with immunosuppressive dosages of corticosteroids, including SOLU-CORTEF. Reactivation can also occur infrequently in corticosteroid-treated patients who appear to have resolved hepatitis B infection.

Screen patients for hepatitis B infection before initiating immunosuppressive (e.g., prolonged) treatment with SOLU-CORTEF. For patients who show evidence of hepatitis B infection, recommend consultation with physicians with expertise in managing hepatitis B regarding monitoring and consideration for hepatitis B antiviral therapy.

Fungal Infections

Corticosteroids, including SOLU-CORTEF, may exacerbate systemic fungal infections; therefore, avoid SOLU-CORTEF use in the presence of such infections unless SOLU-CORTEF is needed to control drug reactions. For patients on chronic SOLU-CORTEF therapy who develop systemic fungal infections, SOLU-CORTEF withdrawal or dosage reduction is recommended.

Amebiasis

Corticosteroids, including SOLU-CORTEF, may activate latent amebiasis. Therefore, it is recommended that latent amebiasis or active amebiasis be ruled out before initiating SOLU-CORTEF in patients who have spent time in the tropics or patients with unexplained diarrhea.

Strongyloides Infestation

Corticosteroids, including SOLU-CORTEF, should be used with great care in patients with known or suspected *Strongyloides* (threadworm) infestation. In such patients, corticosteroid-induced immunosuppression may lead to *Strongyloides* hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicemia.

Cerebral Malaria

Avoid corticosteroids, including SOLU-CORTEF, in patients with cerebral malaria.

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Kaposi's Sarcoma:


Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic conditions. Discontinuation of corticosteroids may result in clinical improvement of Kaposi's sarcoma.

כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה.
העלונים המעודכנים זמינים באתר משרד הבריאות.

<https://www.gov.il/he/service/israeli-drug-index>

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פיזר פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד.
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בברכה,
עידית שלם אבידר
רוקחת ממונה

DocuSigned by:

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