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

אפריל 2021

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכונים בעלון לרופא של התכשיר **SOLU CORTEF 500** :

הרכב וחוזק: Hydrocortisone (as sodium succinate) 500mg

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 בעלון לרופא הוא הסרת חומר משמר מממס התכשיר ותוספת החמרה:

PHARMACEUTICAL FORM
Powder for solution for injection or infusion.
~~**NOT FOR USE IN NEONATES**~~
~~**CONTAINS BENZYL ALCOHOL**~~

DESCRIPTION
Each **4 mL** contains (when mixed):
Hydrocortisone sodium succinate equiv. to 500 mg Hydrocortisone
Monobasic sodium phosphate monohydrate
Dibasic sodium phosphate dried
~~Benzyl alcohol added as preservative~~
Sodium hydroxide
Water for injections
The solvent, as part of the packaging presentation for the ACT-O-VIAL™ system, is comprised of Water for Injection only, and does not contain any preservative.

CONTRAINDICATIONS
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~~SOLU-CORTEF® 500 Sterile Powder is contraindicated for use in premature infants because the formulation contains benzyl alcohol.~~

WARNINGS
…
General:
~~This product contains benzyl alcohol which is potentially toxic when administered locally to neural tissue. Exposure to excessive amounts of benzyl alcohol has been associated with toxicity (hypotension, metabolic acidosis), particularly in neonates, and an increased incidence of kernicterus, particularly in small preterm infants. There have been rare reports of deaths, primarily in preterm infants, associated with exposure to excessive amounts of benzyl alcohol. The amount of benzyl alcohol from medications is usually considered negligible compared to that received in flush solutions containing benzyl alcohol. Administration of high dosages of medications containing this preservative must take into account the total amount of benzyl alcohol administered. The amount of benzyl alcohol at which toxicity may occur is not known. If the patient requires more than the recommended dosages or other medications containing this preservative, the practitioner must consider the daily metabolic load of benzyl alcohol from these combined sources.~~
…
PRECAUTIONS
…
Pregnancy: Teratogenic Effects
Corticosteroids have been shown to be teratogenic in many species when given in doses equivalent to the human dose. Animal studies in which corticosteroids have been given to pregnant mice, rats, and rabbits have yielded an increased incidence of cleft palate in the offspring. There are no adequate and well-controlled studies in pregnant women. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have received corticosteroids

during pregnancy should be carefully observed for signs of hypoadrenalism.
~~This product contains benzyl alcohol as a preservative.~~
~~Benzyl alcohol can cross the placenta.~~
…
Pediatric Use:
~~This product contains benzyl alcohol as a preservative. Benzyl alcohol, a component of this product, has been associated with serious adverse events and death, particularly in pediatric patients. The "gasping syndrome", (characterized by central nervous system depression, metabolic acidosis, gasping respirations, and high levels of benzyl alcohol and its metabolites found in the blood and urine) has been associated with benzyl alcohol dosages >99 mg/kg/day in neonates and low-birth-weight neonates. Additional symptoms may include gradual neurological deterioration, seizures, intracranial hemorrhage, hematologic abnormalities, skin breakdown, hepatic and renal failure, hypotension, bradycardia, and cardiovascular collapse. Although normal therapeutic doses of this product ordinarily deliver amounts of benzyl alcohol that are substantially lower than those reported in association with the "gasping syndrome", the minimum amount of benzyl alcohol at which toxicity may occur is not known. The risk of benzyl alcohol toxicity depends on the quantity administered and the hepatic capacity to detoxify the chemical. Premature and low-birth-weight infants, as well as patients receiving high dosages, may be more likely to develop toxicity. Practitioners administering this and other medications containing benzyl alcohol should consider the combined daily metabolic load of benzyl alcohol from all sources.~~
Hypertrophic cardiomyopathy was reported after administration of hydrocortisone to prematurely born infants, therefore appropriate diagnostic evaluation and monitoring of cardiac function and structure should be performed.

DOSAGE AND ADMINISTRATION
~~NOTE: CONTAINS BENZYL ALCOHOL~~
…

STORAGE CONDITIONS
Store below 25°C.
Use the solution immediately after reconstitution. ~~After reconstitution, store solution at 25°C and protect from light. Unused solution should be discarded after 12 hours.~~
Use solution only if it is clear.

השינוי המודגש ברקע צהוב מהווה החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה.

העלון לרופא נשלח למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות:
https://data.health.gov.il/drugs/index.html#!/byDrug
לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פי אף אי פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, 46725.

בברכה,
גילי קבשה
רוקחת ממונה