פברואר, 2024

הנדון: עדכון עלון לתכשיר Ceftriaxone – VIT (159 42 34699 00)

רופא/ ה נכבד/ ה,

רוקח/ ת נכבד/ ה,

חברת ויטאמד תעשיות פרמצבטיות בע"מ, מבקשת להודיעכם על עדכון העלון לצרכן במתכונת עלון לרופא של התכשיר צפטריאקסון - ויט.

הרכב התכשיר:

CEFTRIAXONE AS DISODIUM HEMIHEPTAHYDRATE 1.0 G/VIAL

התוויות מאושרות:

Ceftriaxone VIT is indicated for the treatment of the following infections in adults and children including term neonates (from birth):-Bacterial Meningitis- Community acquired pneumonia-Hospital acquired pneumonia-Acute otitis media-Intra-abdominal infections-Complicated urinary tract infections (including pyelonephritis)-Infections of bones and joints-Complicated skin and soft tissue infections-Gonorrhoea-Syphilis-Bacterial endocarditis Ceftriaxone VIT may be used:- For treatment of acute exacerbations of chronic obstructive pulmonary disease in adults- For treatment of disseminated Lyme borreliosis (early (stage ll) and late (stagelll) in adults and children including neonates from 15 days of age.- For pre-operative prophylaxis of surgical site infections-In the management of neutropenic patients with fever that is suspected to be due to a ceftriaxone – susceptible bacterial infection- In the treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. Ceftriaxone VIT should be co-administered with other antibacterial agents whenever the possible range of causative bacteria would not fall within its spectrum.

בהודעה זו מפורטים העדכונים המהווים החמרה במידע הבטיחותי בלבד (מסומנים בצבע אדום). למידע מלא,

יש לעיין בעלון.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות בכתובת:

https://israeldrugs.health.gov.il וניתן לקבלו מודפס ע"י פנייה לבעל הרישום:

ויטאמד תעשיות פרמצבטיות בע"מ, ת"ד 114 בנימינה 3055002, ישראל.

בכבוד רב,

העדכונים בעלון לצרכן במתכונת עלון לרופא:

4.4 Special Warnings and precautions for use

Severe cutaneous adverse reactions (Stevens Johnson syndrome or Lyell's syndrome/toxic epidermal necrolysis) and drug reaction with eosinophilia and systemic symptoms (DRESS) which can be life threatening or fatal have been reported in association of ceftriaxone treatment; however, the frequency of these events is not known (see section 4.8).

The presence of ceftriaxone may falsely lower estimated blood glucose values obtained with some blood glucose monitoring systems. Please refer to instructions for use for each system. Alternative testing methods should be used if necessary.

Sodium

Ceftriaxone 1 g powder for solution for injection or infusion contains 83 mg sodium per 1g vial, equivalent to 4.3% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Jarisch-Herxheimer reaction (JHR)

Some patients with spirochete infections may experience a Jarisch-Herxheimer reaction (JHR) shortly after ceftriaxone treatment is started. JHR is usually a self – limiting condition or can be managed by symptomatic treatment. The antibiotic treatment should not be discontinued if such reaction occurs.

Encephalopathy

Encephalopathy has been reported with the use of ceftriaxone (see section

4.8), particularly in elderly patients with severe renal impairment (see section 4.2) or central nervous system disorders. If ceftriaxone-associated encephalopathy is suspected (e.g. decreased level of consciousness, altered mental state, myoclonus, convulsions), discontinuation of ceftriaxone should be considered.

4.8 Undesirable Effects

Immune system Disorders – Jerisch- Herzxheimer Reaction.

Nervous System – Encephalopathy

Hepatobiliary disorders - hepatitis, hepatitis cholestatic.

Skin and subcutaneous tissue disorders: Drug Reaction with eosinophilia and systemic symptoms (DRESS).

Cases of ceftriaxone precipitation in the urinary tract have been reported, mostly in children treated with high doses (e.g., ≥ 80 mg/kg/day or total doses exceeding 10 grams) and who have other risk factors (e.g., dehydration, confinement to bed). This event may be asymptomatic or symptomatic, and may lead to ureteric obstruction and postrenal acute renal failure, but is usually reversible upon discontinuation of ceftriaxone (see section 4.4).