12/2023

CEFTRIAXONE – FRESENIUS

צפטריאקסון – פרזניוס

מרכיב פעיל:

CEFTRIAXONE (AS SODIUM) 1000 MG/VIAL

צורת מינון:

POWDER FOR SOLUTION FOR INJECTION / INFUSION

רופא/ה, רוקח/ת נכבד/ה,
חברת ניאופרם (ישראל) 1996 בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנדון.
העלון עודכן בתאריך דצמבר 2023.

ההתוויה הרשומה לתכשיר בישראל:

Ceftriaxone-Fresenius 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-Fresenius may be used:
- For treatment of acute exacerbations of chronic obstructive pulmonary disease in adults
- For treatment of disseminated Lyme borreliosis [early (stage II) and late (stage III)] 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 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-Fresenius should be co-administered with other antibacterial agents whenever the possible range of causative bacteria would not fall within its spectrum.

Consideration should be given to official guidelines on the appropriate use of antibacterial agents.

בהודעה זו מצוינים השינויים המהותיים בלבד.

מקראה לעדכונים המסומנים:
תוספת -כתב **כחול**
מידע שעבר מקום - כתב ירוק

עדכונים מהותיים נעשו בסעיף הבא בעלון לרופא:

4.4 Special warnings and precautions for use

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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).

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5.2 Pharmacokinetic properties

Absorption

Intramuscular administration

Following intramuscular injection, mean peak plasma ceftriaxone levels are approximately half those observed after intravenous administration of an equivalent dose. The maximum plasma concentration after a single intramuscular dose of 1 g is about 81 mg/l and is reached in 2 - 3 hours after administration. The area under the plasma concentration-time curve after intramuscular administration is equivalent to that after intravenous administration of an equivalent dose.

Intravenous administration

After intravenous bolus administration of ceftriaxone 500 mg and 1 g, mean peak plasma ceftriaxone levels are approximately 120 and 200 mg/l respectively. After intravenous infusion of ceftriaxone, 1 g and 2 g, the plasma ceftriaxone levels are approximately, 150 and 250 mg/l respectively.

קיימים עדכונים נוספים. למידע נוסף יש לעיין בעלון לרופא המעודכן.

בברכה,

עדי יפרח
רוקחת ממונה