09-2022

Cefuroxime -Fresenius 750 mg powder for solution for injection

צפורוקסים-פרזניוס 750 מ"ג אבקה עבור תמיסה להזרקה

חומר פעיל:

Cefuroxime (as sodium salt)	750 MG

צורת מתן : I.M , I.V

Cefuroxime -Fresenius1500mg powder for solution for injection

צפורוקסים-פרזניוס 1500 מ"ג אבקה עבור תמיסה להזרקה

חומר פעיל:

Cefuroxime (as sodium salt)	1500 MG

צורת מתן : I.V

רופא/ה, רוקח/ת נכבד/ה,

- ניאופרם (ישראל) 1996 בע"מ מבקשת להודיע על עדכון העלונים לרופא של התכשירים:

Cefuroxime -Fresenius 750 mg powder for solution for injection
Cefuroxime -Fresenius 1500 mg powder for solution for injection

- העלונים של התכשירים עודכנו ב 09-2022

- בהודעה זו כלולים שינויי בטיחות מהותיים שמופיעים בכחול על רקע צהוב.
טקסט חדש מופיע בכחול , טקסט שהוסר מופיע באדום עם ~~קו חוצה~~ .

להלן נוסח ההתוויה המאושרת לתכשיר:

Treatment of infections due to Cefuroxime susceptible micro -organisms

העדכונים נעשו בסעיפים הבאים:

4.4 Special warning and precautions for use

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Intra-abdominal infections

Due to its spectrum of activity, cefuroxime is not suitable for the treatment of infections caused by Gram-negative non-fermenting bacteria (see section 5.1).

ניאופרם (ישראל) 1996 בע"מ בנין ניאופרם, רח' השילוח 6 ת.ד. 7063 פתח תקוה 4917001
Email: neopharm@neopharmisrael.com פקס: 03-9373716 טל: 03-9373737 www.neopharmgroup.com

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Intracameral use and eye disorders

Cefuroxime is not formulated for intracameral use. Individual cases and clusters of serious ocular adverse reactions have been reported following unapproved intracameral use of cefuroxime sodium compounded from vials approved for intravenous/intramuscular administration. These reactions included macular oedema, retinal oedema, retinal detachment, retinal toxicity, visual impairment, visual acuity reduced, vision blurred, corneal opacity and corneal oedema.

4.5 Interaction with other medicinal products and other forms of interaction

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Other interactions

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Concomitant use with oral anticoagulants may give rise to increased international normalised ratio (INR).

4.6 Fertility , pregnancy and lactation

pregnancy

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Cefuroxime has been shown to cross the placenta and attain therapeutic levels in amniotic fluid and cord blood after intramuscular or intravenous dose to the mother.

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Fertility

There are no data on the effects of cefuroxime sodium on fertility in humans. Reproductive studies in animals have shown no effects on fertility.

4.8 undesirable effects

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System organ class	common	uncommon	Rare	Very rare	Not known
~~Investigations~~ Blood and lymphatic system disorders	Eosinophilia, Neutropenia, Decreased haemoglobin Concentration	~~Eosinophilia~~ Leucopenia ~~Neutopenia~~ ~~Thrombocytopenia~~ Positive Coomb' s test	~~Decreased haemoglobin Concentration,~~ ~~Agranulocytosis~~	~~Haemolytic anaemia~~	~~The use of cefuroxime may be accompanied by a false- positive Coombs test. This may interfere with the performance of cross matching tests with blood~~ Thrombocytopenia Haemolytic anaemia
~~Nervous system disorders~~		~~Headache,~~ ~~diziness~~		~~vertigo,~~ ~~restlessness,~~	

				~~nervousness, confusion~~	
Gastrointestinal disorders	~~Gastrointestinal disturbance such as such diarrhea, nausea and vomiting~~.	Gastrointestinal disturbance			Pseudomonas colitis (see section 4.4)
Renal and urinary disoders	~~Increased levels of creatinine and urea in serum, especially in patients with impaired renal function.~~	~~Acute interstitial Nephritis ;Nephro toxicity; Acute renal tubular necrosis has followed excessive dosage and has also been associated with its use in older patients or those with pre-existing renal impairment(see section 4.2 and 4.4)~~			Elevations in serum creatinine . elevations in blood urea nitrogen and decreased creatinine clearance (see section 4.4)
Skin and subcutaneous tissue disorders	~~Skin rashes, urticaria, pruritus.~~	Skin rashes, urticaria, pruritus	~~Erythema multiforme, *Steven -Johnson* syndrome and toxic epidermal necrolysis~~		Erythema multiforme, toxic epidermal necrolysis and stevens -Johnson syndrome, angioneurotic oedema
Infections and infestations			~~Pseudo-membranous colitis . As with all other Antibiotics prolonged use may lead to secondary superinfections caused by insusceptible organisms e.g Candida ,Enterococci and Clostridium difficile (see section 4.4)~~		Candida overgrowth. Overgrowth of Clostridium difficile
General disorders and administration site conditions	~~Pain at the injection site following intramuscular administration, Thrombophlebitis and pain following intravenous injection,after rapid intravenous administration heat sensations or nausea may occur.~~ Injection site reactions which may include pain and thrombophlebitis		~~Drug fever~~		
Immune system disorders			~~Serum sickness~~	~~Anaphylaxis~~	~~Angioneurotic Oedema~~

				~~(see section 4.4),~~ ~~Cutaneous vasculitis~~	Drug fever , interstitial nephritis, anaphylaxis,Cutaneous vasculitis
Hepatobiliary disorders	Transient rise in liver enzymes	Transient ~~increase~~rise ~~of hepatic enzyme levels (AST,ALTand LDH) and~~ in ~~serum~~bilirubin			~~Jaundice~~

Description of selected adverse reactions
Cephalosporins as a class tend to be absorbed onto the surface of red cell membranes and react with antibodies directed against the drug to produce a positive Coomb's test (which can interfere with cross matching of blood) and very rarely haemolytic anaemia.
Transient rises in serum liver enzymes or bilirubin have been observed which are usually reversible.

Pain at the intramuscular injection site is more likely at higher doses. However it is unlikely to be a cause for discontinuation of treatment.

4.9 Overdose

~~Overdosage of cephalosporins can cause cerebral irritations leading to~~ Overdose can lead to neurological sequelae including encephalopathy, convulsions and coma . ~~There can be sequalae in form of brain damage . Serum levels of cefuroxime can be reduced by haemodyalysis or peritoneal dialysis~~ Symptoms of overdose can occur if the dose is not reduced appropriately in patients with renal impairment (see sections 4.2 and 4.4).

העלונים נשלחו למשרד הבריאות לצורך העלאתם למאגר התרופות שבאתר משרד הבריאות.

קיימים עדכונים נוספים -ניתן לקבל העלונים מודפסים על ידי פניה ישירה לבעל הרישום: ניאופרם (ישראל) 1996 בע"מ, בניין ניאופרם, רח' השילוח 6, ת.ד. 7063, פתח תקווה 4917001. טלפון: 03-9373737, פקס: 03-9373770.

בברכה,
עוז וולך, רוקח ממונה של בעל הרישום