11.2022

עדכון עלון

הנדון:

Zinacef 750 mg

Powder for solution or suspension for injection or infusion.

זינסף 750 מ"ג

אבקה להכנת תמיסה או תרחיף להזרקה או לעירוי

מרכיבים פעילים וחוזקם:

Cefuroxime (as cefuroxime sodium) 750 mg

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת גלקסוסמיתקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלון לצרכן **במתכונת עלון לרופא** של התכשיר שבנדון.

בהודעה זו מצוינים העדכונים המהותיים בלבד.
מקרא לעדכונים המסומנים:
תוספת – כתב **כחול**; תוספת החמרה – כתב **כחול** – מסומן בצהוב מרקר; מידע שהוסר – מסומן בקו אדום חוצה ~~XXX~~

התוויה:

Zinacef is indicated for the treatment of the infections listed below in adults and children, including neonates (from birth)

- Community acquired pneumonia
- Acute exacerbations of chronic bronchitis
- Complicated urinary tract infections, including pyelonephritis
- Soft-tissue infections: cellulitis, erysipelas and wound infections
- Intra-abdominal infections (see section 4.4)
- Prophylaxis against infection in gastrointestinal (including oesophageal), orthopaedic, cardiovascular, and gynaecological surgery (including caesarean section)
- Nose infections for example, sinusitis
- Septic arthritis

עדכונים מהותיים שנעשו בעלון:

3. PHARMACEUTICAL FORM

Powder for solution or suspension for injection or infusion.
Cefuroxime is a white to cream powder to which appropriate amounts of water are added to prepare an off-white suspension for intramuscular use or a yellowish solution for intravenous administration.

(…)

6. PHARMACEUTICAL PARTICULARS

(…)

6.2 Incompatibilities

~~Cefuroxime is compatible with most commonly used intravenous fluids and electrolyte solutions.~~
This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

~~The pH of 2.74% w/v sodium bicarbonate injection BP considerably affects the colour of solutions and therefore this solution is not recommended for the dilution of Zinacef. However, if required, for patients receiving sodium bicarbonate injection by infusion the Zinacef may be introduced into the tube of the giving set.~~

~~Zinacef should not be mixed in the syringe with aminoglycoside antibiotics.~~

6.3 Shelf life

Dry Powder
The expiry date of the product is indicated on the packaging materials.

When reconstituted for injection, it can be stored for 5 hours if stored below 25 °C, or 72 hours if stored 2 to 8 °C.
When reconstituted for infusion, it can be stored for 3 hours if stored below 25 °C, or 72 hours if stored 2 to 8 °C.

From a microbiological point of view, the medicinal product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C unless reconstitution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Store below 25 °C. Keep the vial in the outer carton in order to~~and~~ protect from light.
For storage conditions after reconstitution of the medicinal product, see section 6.3.
~~After constitution, Zinacef should be stored at 2 - 8ºC for no longer than 24 hours~~
~~From a microbial point of view the product should be used immediately.~~

6.5 Nature and contents of container

~~Glass (type I or III) vials~~
Colourless glass vial, with a bromobutyl ~~or fluoro-resin laminated butyl~~ rubber plug~~,~~ and aluminium overseal ~~and~~with flip~~-~~ off ~~cap~~plastic lid, containing 750 ~~mg Zinacef~~ mg, of cefuroxime (as cefuroxime sodium) powder.

6.6 Special precautions for disposal and other handling

(…)
Compatibility
Cefuroxime sodium (5~~-~~ mg/mL) in 5% w/v or 10% w/v xylitol injection may be ~~stored for up to 24 hours at 25ºC.~~used..
Cefuroxime sodium is compatible with aqueous solutions containing up to 1% lidocaine hydrochloride.

Cefuroxime sodium is compatible with the following infusion fluids~~. It will retain potency .:for up to 24 hours at room temperature in:~~

0.9% w/v Sodium Chloride Injection BP
5% Dextrose Injection BP
0.18% w/v Sodium Chloride plus 4% Dextrose Injection BP
5% Dextrose and 0.9% w/v Sodium Chloride Injection BP
5% Dextrose and 0.45% Sodium Chloride Injection
5% Dextrose and 0.225% Sodium Chloride Injection
10% Dextrose Injection
~~10% Invert Sugar in Water for Injection~~
~~Ringer's Injection USP~~
Lactated Ringer's Injection USP
M/6 Sodium Lactate Injection
Compound Sodium Lactate Injection BP (Hartmann's Solution).

The stability of cefuroxime sodium in 0.9% w/v Sodium Chloride Injection BP and in 5% Dextrose Injection is not affected by the presence of hydrocortisone sodium phosphate.

Cefuroxime sodium has also been found compatible ~~for 24 hours at room temperature~~ when admixed in IV infusion with:
Heparin (10 and 50 units/mL) in 0.9% w/v Sodium Chloride Injection BP; Potassium Chloride (10 and 40~~-~~ mEqL) in 0.9% w/v Sodium Chloride Injection BP.

קיימים עדכונים נוספים. למידע נוסף יש לעיין בעלון המעודכן.
העלון נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://israeldrugs.health.gov.il/#!/byDrug

וניתן לקבלו מודפס על-ידי פניה לחברת גלקסוסמיתקליין רח' בזל 25 פתח תקוה בטלפון: 03-9297100.

בברכה,
ארינה שייקביץ
רוקחת ממונה