פייזר פי אף אי פרמצבטיקה ישראל בע"מ
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יוני 2025

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלון לרופא של **ZINFORO** :
זינפורו

הודעה זו מפרטת את המידע הנוגע להרחבת ההתוויה לטיפול ביילדים מגיל לידה ועד גיל חודשיים (שינויים מסומנים בקו תחתון בגוף ההודעה), למידע מלא יש לעיין בעלון המאושר.

המרכיב הפעיל:

CEFTAROLINE FOSAMIL 600 mg

Indicated for:
*Zinforo is indicated in ~~adults and children from age of 2 months~~ for the treatment of the following infections in **neonates**, infants, children, adolescents and adults :*

- *Complicated skin and soft tissue infections (cSSTI)*
- *Community-acquired pneumonia (CAP)*

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

להלן העדכונים העיקריים בעלון לרופא:

4.2 Posology and method of administration

Posology

The recommended durations of treatment are 5-14 days for cSSTI and 5-7 days for CAP.

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Table 2 Dosage in paediatric patients with normal renal function, creatinine clearance (CrCL) > 50 mL/min*

Indications	Age group	Posology (mg/infusion)	Infusion time (minutes)/Frequency
Complicated skin and soft tissue infections (cSSTI) Community-acquired pneumonia (CAP)	Adolescents aged from 12 to < 18 years with bodyweight ≥ 33 kg	600 mg	60/every 12 hours
	Adolescents aged from 12 years to < 18 years bodyweight < 33 kg **and** children ≥ 2 years to < 12 years	12 mg/kg to a maximum of 400 mg	60/every 8 hours
	Infants ≥ 2 months to < 2 years	8 mg/kg	60/every 8 hours
	Neonates from birth to < 2 months[a, b]	**6 mg/kg**	**60/every 8 hours**

* Calculated using the Schwartz formula (in mL/min/1.73 m²) for paediatric patients.

[a] Neonatal recommendations are based on pharmacokinetic and pharmacodynamic analyses only. See sections 4.4 and 5.1.

[b] Based on preterm neonates at least 34 weeks gestational age and 12 days postnatal age

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Special populations

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Dose recommendations for **neonates (at least 34 weeks gestational age and 12 days postnatal age),** infants**,** children and adolescents are based on pharmacokinetic (PK) modelling.

There is insufficient information to recommend dosage adjustments in adolescents aged from 12 to < 18 years with bodyweight < 33 kg and in children aged from 2 to 12 years with End-stage renal disease (ESRD).

There is insufficient information to recommend dosage adjustments in paediatric patients ~~children aged from 2 months to~~ < 2 years with moderate or severe renal impairment or ESRD

4.4 Special warnings and precautions for use

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The recommended dosage of Zinforo shown in Table 2 for paediatric patients < 2 months of age are based on pharmacokinetic-pharmacodynamic modelling and simulation.

4.8 Undesirable effects

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Paediatric population

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In addition, the safety assessment in neonates is based on the safety data from 2 trials in which 34 patients (age range from birth to less than 60 days) received Zinforo; 23 of these patients received only a single dose of Zinforo. Overall, the adverse events reported in these studies were consistent with the known safety profile for Zinforo.

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5.2 Pharmacokinetic properties

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Paediatric population

Dose adjustments are required for neonates, infants, children ~~aged from 2 months to < 12 years~~ and ~~for~~ adolescents ~~aged 12 to < 18 years~~ with bodyweight < 33 kg (see section 4.2). ~~The safety and efficacy of Zinforo in children aged birth to < 2 months have not been established.~~

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כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה. העלונים המעודכנים זמינים באתר משרד הבריאות.

https://www.gov.il/he/service/israeli-drug-index

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר PFE פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133 הרצליה פיתוח, 46725.

בברכה,
עידית שלם אבידר
רוקחת ממונה

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