

רופא/ה, רוקח/ת נכבד/ה,

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

הודעה זו מפרטת את המידע הנוגע לשינוי משטר מינון, הוספת מידע לגבי זמני עירוי קצרים של 5 דקות (שינויים מסומנים בקו תחתון בגוף ההודעה), למידע מלא יש לעיין בעלון המאושר.

המרכיב הפעיל:

CEFTAROLINE FOSAMIL 600 mg

Indicated for:

Zinforo is indicated for the treatment of the following infections in neonates, infants, children, adolescents and adults (see sections 4.4 and 5.1):

- *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.

Table 1 Dosage in adults with normal renal function, creatinine clearance (CrCL) > 50 mL/min

Indications	Posology (mg/infusion)	Infusion time (minutes)/Frequency
<u>Standard dose^a</u> Complicated skin and soft tissue infections (cSSTI) Community-acquired pneumonia (CAP)	600 mg	<u>5 – 60^b</u> /every 12 hours

^a For patients with supranormal renal clearance receiving the standard dose, an infusion time of 60 minutes may be preferable.

^b Infusion times of less than 60 minutes recommendations are based on pharmacokinetic and pharmacodynamic analyses only. See sections 4.4 and 5.1.

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
<u>Standard dose^{a, c}</u>	Adolescents aged from 12 to < 18 years with bodyweight ≥ 33 kg	600 mg	<u>5–60^b</u> /every 12 hours
Complicated skin and soft tissue infections (cSSTI)	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	<u>5–60^b</u> /every 8 hours
Community-acquired pneumonia (CAP)	Infants ≥ 2 months to < 2 years	8 mg/kg	<u>5–60^b</u> /every 8 hours
	Neonates from birth to < 2 months ^{b, c, d}	6 mg/kg	60/every 8 hours

^a For patients with supranormal renal clearance receiving the standard dose, an infusion time of 60 minutes may be preferable.

^b Infusion times of less than 60 minutes recommendations are based on pharmacokinetic and pharmacodynamic analyses only. See sections 4.4 and 5.1.

^c Neonatal recommendations are based on pharmacokinetic and pharmacodynamic analyses only. See sections 4.4 and 5.1.

^d Based on preterm neonates at least 34 weeks gestational age and 12 days postnatal age

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

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Special populations

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Table 3 Dosage in adults with impaired renal function, creatinine clearance (CrCL) ≤ 50 mL/min

Indications	Creatinine clearance (mL/min) ^a	Posology (mg/infusion)	Infusion time (minutes)/Frequency
<u>Standard dose</u>	> 30 to ≤ 50	400 mg	<u>5–60^b</u> /every 12 hours
Complicated skin and soft tissue infections(cSSTI)	≥ 15 to ≤ 30	300 mg	
Community-acquired pneumonia (CAP)	ESRD, including haemodialysis ^b	200 mg	

Indications	Creatinine clearance (mL/min) ^a	Posology (mg/infusion)	Infusion time (minutes)/Frequency
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^a Calculated using the Cockcroft-Gault formula for adults. Dose is based on CrCL. CrCL should be closely monitored and the dose adjusted according to changing renal function.

^b Ceftaroline is haemodialyzable; thus Zinforo should be administered after haemodialysis on haemodialysis days.

^c Infusion times of less than 60 minutes recommendations are based on pharmacokinetic and pharmacodynamic analyses only. See sections 4.4 and 5.1.

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Table 4 Dosage in paediatric patients with impaired renal function, creatinine clearance (CrCL) ≤ 50 mL/min

Indications	Age group	Creatinine clearance (mL/min) ^a	Posology (mg/infusion)	Infusion time (minutes)/Frequency
<u>Standard dose</u>	Adolescents aged from 12 to < 18 years with bodyweight ≥ 33 kg	> 30 to ≤ 50	400 mg	5–60 ^b /every 12 hours
		≥ 15 to ≤ 30	300 mg	
		ESRD, including haemodialysis ^b	200 mg	
Complicated skin and soft tissue infections (cSSTI)	Adolescents aged from 12 years to < 18 years bodyweight < 33 kg	> 30 to ≤ 50	8 mg/kg to a maximum of 300 mg	5–60 ^b /every 8 hours
		≥ 15 to ≤ 30	6 mg/kg to a maximum of 200 mg	
Community-acquired pneumonia (CAP)	and children ≥ 2 years to < 12 years			

^a Calculated using the Schwartz formula for paediatric patients (in mL/min/1.73 m²). Dose is based on CrCL. CrCL should be closely monitored and the dose adjusted according to changing renal function.

^b Ceftaroline is haemodialyzable; thus Zinforo should be administered after haemodialysis on haemodialysis days.

^c Infusion times of less than 60 minutes recommendations are based on pharmacokinetic and pharmacodynamic analyses only. See sections 4.4 and 5.1.

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Method of administration

Intravenous use. Zinforo is administered by intravenous infusion over 5 to 60 minutes for standard dose in infusion volumes of 50 mL, 100 mL or 250 mL (see section 6.6). Infusion related reactions (such as phlebitis) can be managed by prolonging the infusion duration.

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4.4 Special warnings and precautions for use

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Infusion times of less than 60 minutes are based on pharmacokinetic and pharmacodynamic analyses only.

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

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

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פיזור פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133 הרצליה, 4672509.

בברכה,
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רוקחת ממונה