מאי 2022

הנדון: **עדכון עלון של התכשירים:**

Fortum 1 gram
Fortum 2 gram
Powder for solution for injection or infusion

מרכיבים פעילים וחוזקם:

Fortum 1 gram: ceftazidime (as pentahydrate) 1 g per vial
Fortum 2 gram: ceftazidime (as pentahydrate) 2 g per vial

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

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

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

התוויה:

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

- Nosocomial pneumonia
- Broncho-pulmonary infections in cystic fibrosis
- Bacterial meningitis
- Chronic suppurative otitis media
- Malignant otitis externa
- Complicated urinary tract infections
- Complicated skin and soft tissue infections
- Complicated intra-abdominal infections
- Bone and joint infections
- Peritonitis associated with dialysis in patient on CAPD.

Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.
Ceftazidime may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.
Ceftazidime may be used in the peri-operative prophylaxis of urinary tract infections for patients undergoing transurethral resection of the prostate (TURP).
The selection of ceftazidime should take into account its antibacterial spectrum, which is mainly restricted to aerobic Gram negative bacteria (see sections 4.4 and 5.1)
Ceftazidime should be co-administered with other antibacterial agents whenever the possible range of causive bacteria would not fall within its spectrum of activity.
Consideration should be given to official guidelines on the appropriate use of antibacterial agents.

עדכונים מהותיים שנעשו בעלון (עלון לצרכן במתכונת עלון לרופא):

4.2 Posology and method of administration

Posology

Table 1: Adults and children ≥ 40 kg

Intermittent Administration	
Infection	Dose to be administered
Broncho-pulmonary infections in cystic fibrosis	100 to 150 mg/kg/day every 8 h, maximum 9 g per day[1]
Febrile neutropenia	2 g every 8 h
Nosocomial pneumonia	
Bacterial meningitis	

Bacteraemia*	
Bone and joint infections	1-2 g every 8 h
Complicated skin and soft tissue infections	
Complicated intra-abdominal infections	
Peritonitis associated with dialysis in patients on CAPD	
Complicated urinary tract infections	1-2 g every 8 h or 12 h
Per-operative prophylaxis for transurethral resection of prostate (TURP)	1 g at induction of anaesthesia, and a second dose at catheter removal
Chronic suppurative otitis media	1 g to 2 g every 8 h
Malignant otitis externa	
Continuous infusion	
Infection	Dose to be administered
Febrile neutropenia	Loading dose of 2 g followed by a continuous infusion of 4 to 6 g every 24 h[1] The infusion of any unit of dissolved drug shall last no longer than 9h (see section 6.3). Therefore, following reconstitution, the unit dose in the infusion fluid should be administered within 9 h, for example for 8 g per day: 2 g loading dose followed by 2 g continuous infusion every 8 h.
Nosocomial pneumonia	
Broncho-pulmonary infections in cystic fibrosis	
Bacterial meningitis	
Bacteraemia*	
Bone and joint infections	
Complicated skin and soft tissue infections	
Complicated intra-abdominal infections	
Peritonitis associated with dialysis in patients on CAPD	
[1]In adults with normal renal function 9 g/day has been used without adverse effects. *When associated with, or suspected to be associated with, any of the infections listed in 4.1.	

(…)

Haemodialysis

The serum half-life during haemodialysis ranges from 3 to 5 h.

Following each haemodialysis period, the maintenance dose of ceftazidime recommended in the tables 3 & 4~~5 & 6~~ should be repeated.

4.5. Interaction with other medicinal products and other forms of interaction

(…)

~~In common with other antibiotics, ceftazidime may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.~~

5.1 Pharmacodynamic properties

(…)

Species for which acquired resistance may be a problem
(…)
Gram-positive aerobes: *Staphylococcus aureus*£ *Streptococcus* ~~*Staphylococcus*~~ *pneumoniae*[£££] *Viridans group streptococcus*
(…)

7. Manufacturer

Glaxo Smithkline Trading Services Limited

12 Riverwalk , Citywest business campus, Dublin 24, Ireland

~~GlaxoSmithKline Manufacturing S.p.A., Verona, Italy.~~

קיימים עדכונים נוספים. למידע נוסף יש לעיין בעלון המעודכן.

העלון נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:

https://data.health.gov.il/drugs/index.html#/byDrug

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

בברכה,

ארינה שייקביץ

רוקחת ממונה