Ertapenem for Injection ErtaGold® एट्टांगोल्ड soo भवा / । वा

Infection ^c	Daily Dose (IV or IM) Adults and Pediatric Patients 13 years of age and older	Daily Dose (IV or IM) Pediatric patients 3 Months to 12 years of age	Recommended Duration of Total Antimicrobial Treatment			
Complicated intra- abdominal infection	1g	15 mg/kg twice daily"	5 to 14 days			
Complicated skin and Skin structure infection, Including diabetic foot infections	1g	15 mg/kg twice daily ⁰	7 to 14 days!			
Community acquired pneumonia	1g	15 mg/kg twice daily ^e	10 to 14 daysŦ			
Complicated urinary tract infections	1g	15 mg/kg twice daily"	10 to 14 daysŦ			
Acute pelvic infections	1g	15 mg/kg twice daily ^e	3 to 10 days			
Post surgical gynecologic infections	1g	15 mg/kg twice daily*	3 to 10 days			
Bacterial septicemia	1g	15 mg/kg twice daily"	3 to 14 days			

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Males: CL_o = (Weight in kg) (140 - age in years)

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Adverse Events	Ertapenem* 1 g daily (N=802)	Piperacillin/ Tazobactam 3.375g q6h (N=774)	Ertapenem† 1 g daily (N=1152)	Ceftriaxone 1 or 2g (N=942)
Local:				
Extravasation	1.9	1.7	0.7	1.1
Infused vein complication	7.1	7.9	5.4	6.7
Phlebitis/ Thrombophlebitis	1.9	2.7	1.6	2.0
Systemic:				
Asthenia/ fatigue	1.2	0.9	1.2	1.1
Death	2.5	1.6	1.3	1.6
Edema/swelling	3.4	2.5	2.9	3.3
Fever	5.0	6.6	2.3	3.4
Abdominal pain	3.6	4.8	4.3	3.9
Chest pain	1.5	1.4	1.0	2.5
Hypertension	1.6	1.4	0.7	1.0
Hypotension	2.0	1.4	1.0	1.2
Tachycardia	1.6	1.3	1.3	0.7
Acid regurgitation	1.6	0.9	1.1	0.6
Oral candidiasis	0.1	1.3	1.4	1.9
Constipation	4.0	5.4	3.3	3.1
Diarrhoea	10.3	12.1	9.2	9.8
Dyspepsia	1.1	0.6	1.1	1.6
Nausea	8.5	8.7	6.4	7.4
Vomiting	3.7	5.3	4.0	4.0
Leg pain	1.1	0.5	0.4	0.3
Anxiety	1.4	1.3	0.8	1.2
Altered mental status	5.1	3.4	3.3	2.5
Dizziness	2.1	3.0	1.5	2.1
Headache	5.6	5.4	6.8	6.9
Insomnia	3.2	5.2	3.0	4.1
Cough	1.6	1.7	1.3	0.5
Dyspnea	2.6	1.8	1.1	2.4
Pharyngitis	0.7	1.4	1.1	0.6
Rales/rhonchi	1.1	1.0	0.5	1.0
Respiratory distress	1.0	0.4	0.2	0.2
Erythema	1.6	1.7	1.2	1.2
Pruritus	2.0	2.6	1.0	1.9
Rash	2.5	3.1	2.3	1.5
Vaginitis	1.4	1.0	3.3	3.7
*Includes phase IIb/III complicated i infections and acute pelvic infectior †Includes phase IIb/III community a and phase IIa studies. ‡Includes agitation, confusion, diso somnolence, stupor	studies. cquired pneumon rientation, decrea	ia and complica	ted urinary tract ty, changed mer	infections,

BACK 100x300 mm

Incidence (%) of Adverse Experiences Reported during Study Therapy plus 14-day folllow up in 2.1.0% of Adult Patients Treated with ertapenem for Prophylaxis of Surgical Site Infections following Elective Colorectal Surgery						
Adverse Events	Ertapenem 1 g (N=476)	Cefotetan 2 gn (N=476)				
Anemia	5.7	6.9				
Small intestinal obstruction	2.1	1.9				
Cellulitis	1.5	1.5				
C. difficile infection or colitis	1.7	0.6				
Pneumonia	2.1	4.0				
Postoperative infection	2.3	4.0				
Urinary tract infection	3.8	5.5				
Wound infection	6.5	12.4				
Anastomotic leak	1.5	1.3				
Seroma	1.3	1.9				
Wound complication	2.9	2.3				
Wound dehiscence	1.3	1.5				
Wound secretion	1.9	2.1				
Dysuria	1.1	1.3				
Atelectasis	3.4	1.9				

Adverse Events	Ertapenem * 1 (N=384)	Ceftriaxone* (N=100)	Ticarcillin/Clavulanate 1 (N=24)
Local:			
Infusion Site Erythema	3.9	3.0	8.3
Infusion Site Induration	1.0	1.0	0.0
Infusion Site Pain	7.0	4.0	20.8
Infusion Site Phlebitis	1.8	3.0	0.0
Infusion Site Swelling	1.8	1.0	4.2
Infusion Site Warmth	1.3	1.0	4.2
Systematic:			
Abdominal Pain	4.7	3.0	4.2
Upper Abdominal Pain	1.0	2.0	0.0
Constipation	2.3	0.0	0.0
Diarrhea	11.7	17.0	4.2
Loose Stools	2.1	0.0	0.0
Nausea	1.6	0.0	0.0
Vomiting	10.2	11.0	8.3
Pyrexia	4.9	6.0	8.3
Abdominal Abscess	1.0	0.0	4.2
Herpes Simplex	1.0	1.0	4.2
Nasopharyngitis	1.6	6.0	0.0
Upper Respiratory Tract Infection	2.3	3.0	0.0
Viral Pharyngitis	1.0	0.0	0.0
Hypothermia	1.6	1.0	0.0
Dizziness	1.6	0.0	0.0
Headache	4.4	4.0	0.0
Cough	4.4	3.0	0.0
Wheezing	1.0	0.0	0.0
Dermatitis	1.0	1.0	0.0
Pruritis	1.6	0.0	0.0
Diaper Dermatitis	4.7	4.0	0.0
Rash	2.9	2.0	8.3

Ertapenem in Clinical Studies								
Adverse laboratory experiences	Ertapenem ⁴ 1 g daily (n =766)	Piperacillin/ Tazobactum 3.375g q ¹¹ (n =755)	Ertapenem ¹ 1g daily (n =1122)	Cefriaxone 1 or 2g daily (n'=920)				
ALT increased	8.8	7.3	8.3	6.9				
AST increased	8.4	8.3	7.1	6.5				
Serum albumin decreased	1.7	1.5	0.9	1.6				
Serum alkaline phosphate increased	6.6	7.2	4.3	2.8				
Serum creatinine increased	1.1	2.7	0.9	1.2				
Serum glucose increased	1.2	2.3	1.7	2.0				
Serum potassium decreased	1.7	2.8	1.8	2.4				
Serum potassium increased	1.3	0.5	0.5	0.7				
Total serum bilirubin increased	1.7	1.4	0.6	1.1				
Eosinophil increased	1.1	1.1	2.1	1.8				
Hematocrit decreased	3.0	2.9	3.4	2.4				
Hemaglobin decreased	4.9	4.7	4.5	3.5				
Platelet count decreased	1.1	1.2	1.1	1.0				
Platelet count increased	6.5	6.3	4.3	3.5				
Segmented neutrophils decreased	1.0	0.3	1.5	0.8				
Prothrombin time increased	1.2	2.0	0.3	0.9				
WBC decreased	0.8	0.7	1.5	1.4				
Urine RBCs increased	2.5	2.9	1.1	1.0				
Urine WBCs increased	2.5	3.2	1.6	1.1				

Phase IIa studies tional laboratory experiences that were reported during therapy >0.1% but <1.0% of pati-ted with ertapenem in clinical studies include: increase in BUN, direct and indirect serum sodi

Incidence* (%) of Specific Laboratory Adverse Experiences Reported during Study Therapy plus 14-Day follow up in > 1.0% of pediatric Patients Treated with Extapenem in Clinical Studies						
Adverse laboratory experiences	Ertapenem (n =379)	Ceftriaxone (n'=97)	Ticarcillin / Clavulanate (n'=24)			
ALT increased	3.8	1.1	4.3			
Alkaline phosphate increased	1.1	0.0	0.0			
AST increased	3.8	1.1	4.3			
Eosinophil count increased	1.1	2.1	0.0			
Neutrophil count Decreased	5.8	3.1	0.0			
Platelet count increased	1.3	0.0	8.7			

Average plasma concentrations (mcg/mL)									
Dose/Route	0.5 hr	1 hr	2 hr	4 hr	6 hr	8 hr	12 hr	18 hr	24 hr
1g IV*	155	155	83	48	31	20	9	3	1
1g IM	33	53	67	57	40	27	13	4	2

Age group	Dose		Average plasma concentrations(mcg/ml)						
		0.5 hr	1 hr	2 hr	4 hr	6 hr	8 hr	12 hr	24 hr
3 to 23	months								
	15mg/kg	103.8	57.3	43.6	23.7	13.5	8.2	2.5	
	20mg/kg	126.8	87.6	58.7	28.4		12.0	3.4	0.4
	40mg/kg ""	199.1	144.1	95.7	58.0		20.2	7.7	0.6
2 to 13	years								
	15mg/kg	113.2	63.9	42.1	21.9	12.8	7.6	3.0	
	20mg/kg	147.6	97.6	63.2	34.5		12.3	4.9	0.5
	40mg/kg	241.7	152.7	96.3	55.6		18.8	7.2	0.6
13 to 1	7 years								
	20mg/kg "/	170.4	98.3	67.8	40.4		16.0	7.0	1.1
	1g'	155.9	110.9	74,8		24.0		6.2	
	40mg/kg	255.0	188.7	127.9	76.2		31.0	15.3	2.1

To gettive wavesteroid or despenses (meg./ml.jachievel in adult site bitiser fluid at each sampling point on the third day of a gone daily intravenous does 1.00 to 1.