

Clinical trial results: An Open-Label, Parallel-Group Study to Evaluate the Single-Dose Pharmacokinetics and Safety of Doripenem in Pediatric Patients 3 Months to 17 Years of Age, Inclusive

Summary

Results information	
Trial information	
Trial identification	
Additional study identifiers	

Sponsors	

Paediatric regulatory details	

Results analysis stage		

General information about the trial

Population of trial subjects	
Subjects enrolled per country	

Subjects enrolled per age group	

Subject disposition

Recruitment Pre-assignment

Period 1	
Arms	
Arm title	

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Arm title	

Arm title	

Arm title	

Number of subjects in period 1		

Number of subjects in period 1	



Reporting group values		
		1

End points reporting groups			
sma Concentration (Cmax) of Doripenem			
1			

End point values		

Primary: Time to Reach Maximum	Observed Plasma	Concentration	(Tmax) of
Doripenem			

End point values		

Primary: Area Under the Plasma Concentration-Time Curve From Time Zero to Infinite Time (AUC[0-infinity]) of Doripenem			

End point values		

Primary: Plasma Elimination Half-Life (t1/2) of Doripenem		

End point values		

End point values		

Primary: Systemic Clearance (CL) of Doripenem		

End point values		

Primary: Renal Clearance (CLr) of Doripenem		

End point values		

Primary: Creatinine clearance [CLcr] of Doripenem		

End point values		

Primary: Total amount excreted into urine [Ae] of Doripenem			

End point values		

Primary: Maximum Observed Plasma Concentration (Cmax) of Metabolite Doripenem-M-1

End point values		

Primary: Time to Reach Maximum Observed Plasma Concentration (Tmax) of Metabolite Doripenem-M-1				

End point values		

Primary: Area Under the Plasma Concentration-Time Curve From Time Zero to Infinite Time (AUC[0-infinity]) ofInfinite Time (AUC[0-infinity]) of Metabolite Doripenem-M-1

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End point values		

Primary: Plasma Elimination Half-Life (t1/2) of Metabolite Doripenem-M-1		
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End point values		

Primary: Total amount excreted into urine [Ae] of Metabolite Doripenem-M-1			

End point values		

Adverse events information

Dictionary used
Reporting groups

Serious adverse events		

Serious adverse events		

Non-serious adverse events		



Non-serious adverse events		



More information

Substantial protocol amendments (globally)

Date	Amendment

Interruptions (globally)

Limitations and caveats