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The effect of food on ritonavir bioavailability following administration of ritonavir 100 mg film-coated tablet in healthy adult subjects

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Purpose of the study

A new 100 mg tablet formulation of ritonavir has been developed that would not require refrigeration. This study compared the single-dose bioavailability of the final ritonavir 100 mg tablet formulation following a moderate-fat or high-fat meal relative to that under fasting conditions.

Methods

This was a single-dose, open-label, 3-period crossover study with a randomized, crossover design. Healthy male and female subjects (n = 27) participated in the study. Serial blood samples were collected for 36 hours after each dose. Ritonavir AUC from time 0 to the last measurable concentration (AUCt) and from time 0 to infinity (AUCinf), maximum plasma concentration (Cmax), and time of Cmax (Tmax) were determined using noncompartmental methods. The bioavailability of the tablet following a meal relative to the fasting condition was assessed by the two one-sided tests procedure using 90% confidence intervals (CI). Safety was assessed throughout the study.

Summary of results

Table 1 presents the food effect results of the ritonavir pharmacokinetic parameters following administration of the ritonavir tablet.

Ritonavir Cmax and AUC were approximately 20–24% lower when dosed following a meal compared to administration under fasting conditions. The slight difference in Tmax is consistent with delayed gastric emptying following a meal. Overall, the tablet formulation was generally safe and well tolerated.

Conclusion

Overall, ritonavir pharmacokinetics after administration of the tablet are slightly affected by meal content (with moderate or high fat).

Table 1:

		Arithmetic Mean ± SD		Relative Bioavailability	
	Pharmacokinetic Parameter	**Test (Meal)**	**Reference (Fasting)**	**Point Estimate #**	**90% CI**
	Ritonavir Dosed Under Moderate Fat Meal Condition (20–30% Fat, N = 26)				
Moderate Fat vs. Fasting	Cmax (mg/mL)	0.47 ± 0.27	0.60 ± 0.31	0.784	0.675 – 0.910
	Tmax (h)	4.2 ± 1.2	3.2 ± 1.2		
	AUCt (mg*h/mL)	3.8 ± 2.0	4.6 ± 2.0	0.791	0.719 – 0.870
	AUCinf (mg*h/mL)	3.9 ± 2.1	4.7 ± 2.0	0.798	0.726 – 0.877
	Ritonavir Dosed Under High Fat Meal Condition (50% Fat, N = 25)				
High Fat vs. Fasting	Cmax (mg/mL)	0.44 ± 0.21	0.60 ± 0.31	0.765	0.657 – 0.892
	Tmax (h)	4.8 ± 1.1	3.2 ± 1.2		
	AUCt (mg*h/mL)	3.5 ± 1.6	4.6 ± 2.0	0.763	0.692 – 0.841
	AUCinf (mg*h/mL)	3.6 ± 1.7	4.7 ± 2.0	0.773	0.702 – 0.851

#Antilogarithm of the difference (test minus reference) of the least square means for logarithms.