

The study listed may include approved and non-approved uses, formulations or treatment regimens. The results reported in any single study may not reflect the overall results obtained on studies of a product. Before prescribing any product mentioned in this Register, healthcare professionals should consult prescribing information for the product approved in their country.

Study No: AS-03			
Title: Alosetron (GR68755): Phase I study (evaluation of the effect of food in healthy volunteer).			
Rationale: The study was undertaken to investigate the effect of food on the pharmacokinetics of alosetron.			
Phase: I			
Study Period: July 1992 – August 1992.			
Study Design: An open-label, randomised, crossover study.			
Centres: One centre in Japan.			
Indication: None.			
Treatment: Subjects received a single oral dose of alosetron 1 mg administered after a 12 h fast and, on a separate day, a single oral dose of alosetron 1 mg 30 minutes after a standardised breakfast, in a random order. Subjects were permitted to drink water, but no other food or drink was allowed until 4 h after drug intake in the fasted state. There was a 1-week washout period between the two treatment days.			
Objectives: To study the effect of food on the pharmacokinetics of alosetron.			
Statistical Methods: The Gauss-Newton method was used to calculate half-life ($t_{1/2}$), area under the plasma concentration-time curve from time zero to infinity (AUC_{∞}), maximum plasma concentration (C_{max}) and time to C_{max} (t_{max}). Mean values and standard deviations were calculated for each parameter and comparisons between the fed and fasted state were made using a Student's t-test.			
Study Population: Healthy male subjects aged 20-39years.			
Number of Subjects:			
Planned N	8		
Dosed N	8		
Completed n (%)	8 (100)		
Total Number Subjects Withdrawn N (%)	0		
Withdrawn due to adverse events, n (%)	0		
Withdrawn due to lack of efficacy, n (%)	Not applicable		
Withdrawn due to other reasons, n (%)	0		
Demographics			
N (ITT)	8		
Females : Males	0:8		
Age range in years	20 – 26		
Mean Weight in kg (SD)	58.7 (5.4)		
Japanese n (%)	8 (100)		
Pharmacokinetic Endpoints:			
Parameter, mean (SD)	Alosetron 1 mg (fasted)	Alosetron 1 mg (after meal)	P-value
C_{max} (ng/nL)	3.89 (2.33)	3.25 (1.39)	0.199
AUC_{∞} (ng.h/mL)	13.34 (8.26)	11.04 (3.65)	0.254
T_{max} (h)	1.63 (0.37)	2.01 (0.57)	0.003
$t_{1/2}$ (h)	1.32 (0.17)	1.27 (0.14)	0.591
The mean (SD) 24-h urinary excretion of unmetabolised alosetron was 6.69% (4.41) when administered in the fasted state and 9.15% (9.07) when administered after food.			
Safety results: Adverse events (AEs) were collected throughout the study.			
Adverse Events:	Alosetron 1 mg (fasted)	Alosetron 1 mg (after meal)	
N (ITT)	8	8	
No. subjects with AEs n (%)	2 (25)	3 (37)	
Most Frequent AEs			
Sleepiness	1 (12)	2 (25)	
Serious Adverse Events, n (%) [n considered by the investigator to be related, possibly related, or probably related to study medication]:			

No. subjects with SAEs n (%) -includes fatal and non-fatal events	0	0
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Publications: No publication
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