AstraZeneca

DRUG PRODUCT		**Synopsis**	(FOR NATIONAL AUTHORITY USE ONLY)
DRUG SUBSTANCE	H 199/18	REFERRING TO PART OF THE DOSSIER	
DOCUMENT NO.	SH-QBE-0059		
VERSION NO.	01		
STUDY CODE	SH-QBE-0059		
DATE	30 November, 1999		

A comparative study on 40 mg H 199/18 and 30 mg lansoprazole with regard to effect on 24-hour intragastric pH in healthy subjects

STUDY CENTRE

Single centre study

PUBLICATION (REFERENCE)

This section is not applicable.

STUDY PERIOD

- DATE OF FIRST SUBJECT ENROLLED 31 May, 1999
- DATE OF LAST SUBJECT COMPLETED 19 July, 1999

PHASE OF DEVELOPMENT

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OBJECTIVES

The objective was to compare the effect on 24-hour intragastric pH of 40 mg H 199/18 and 30 mg lansoprazole on day 5 following repeated once-daily administration in healthy male and female subjects.

STUDY DESIGN

Open, randomised, two-way cross-over study

DIAGNOSIS AND MAIN CRITERIA FOR INCLUSION/EXCLUSION

Healthy male and female subjects

TEST PRODUCT, BATCH NUMBER, DOSAGE AND MODE OF ADMINISTRATION

H 199/18 capsule 40 mg, batch no. H 1222-04-01-08, oral dose of 40 mg o.m.

COMPARATOR PRODUCT, BATCH NUMBER, DOSAGE AND MODE OF ADMINISTRATION

Lansoprazole (PREVACID®) capsule 30 mg batch no. H 0995-05-01-01,
oral dose of 30 mg o.m.

DURATION OF TREATMENT

Two periods of 5 days separated by a wash-out period of at least 14 days

MAIN MEASUREMENTS AND VARIABLES:

- PHARMACOKINETIC

  This section is not applicable.

- PHARMACODYNAMIC

  The percentage of time with intragastric pH>4 and intragastric pH>3 for 24 hours.

- SAFETY

  Adverse Events (AE), laboratory assessments, ECG and physical examination.

METHODS FOR DATA EVALUATION

The percentage of time with intragastric pH>4 and percentage time with intragastric pH>3 during the 24-hour period following drug administration was analysed separately, using a mixed model ANOVA with fixed effects for period, sequence and treatment and a random effect for subject within sequence. The mean for each treatment and the mean treatment difference was estimated with 95% confidence intervals.

SUBJECTS

	Total
No. planned	24
No. randomised and treated	24
Males/Females	19/5
Mean age (range)	26.6 years (21-36)
No. analysed for pharmacodynamics	20
No. analysed for safety	24
No. completed	22

SUMMARY

- PHARMACOKINETIC RESULTS

This section is not applicable.

- PHARMACODYNAMIC RESULTS

The difference in the percentage of time with intragastric pH>4 on day 5 between 40 mg H 199/18 and 30 mg lansoprazole was 12.4% (CI; 7.4% to 17.5%). The corresponding difference in the percentage of time with intragastric pH>3 was 9.3% (CI; 4.9 to 13.7).

- SAFETY RESULTS

Ten adverse events was reported for 5 of the 24 subjects who was given H 199/18 and 7 AEs was reported for 6 of the 22 subjects given lansoprazole. The adverse events reported was of mild to moderate intensity.

DATE OF THE REPORT

30 November, 1999