AstraZeneca

DRUG PRODUCT	Losec®	**Synopsis**	(FOR NATIONAL AUTHORITY USE ONLY)
DRUG SUBSTANCE(S)	Omeprazole	REFERRING TO PART	
DOCUMENT NO.	CR-I-598E	OF THE DOSSIER	
VERSION NO.	01		
STUDY CODE	I-598E		
DATE	06 March, 2001		
DRAFT NO.	02		

Omeprazole in the Long Term Management of Duodenal Ulcers

STUDY CENTRE(S)

A single centre at Rotherham District General Hospital, UK.

PUBLICATION (REFERENCE)

There was no publication at the time of the report.

STUDY PERIOD

- DATE OF FIRST PATIENT ENROLLED: March 1992
- DATE OF LAST PATIENT COMPLETED: May 1997

PHASE OF DEVELOPMENT

Therapeutic use

OBJECTIVES

The study was designed to investigate the efficacy and safety of omeprazole 20 mg once daily given for the long-term management of duodenal ulcer.

STUDY DESIGN

Patients who completed I-598 (in remission with maintenance treatment in MP1 or end of healing course in RH2) entered this extension study and were treated openly with omeprazole 20 mg o.d. Any patient who relapsed up to and including 24 months was rehealed with omeprazole 40 mg o.d for 8-12 weeks followed by omeprazole 20 mg o.d.

DIAGNOSIS AND MAIN CRITERIA FOR INCLUSION/EXCLUSION

Endoscopically verifiable duodenal ulcer and high risk factor for duodenal ulcer as given in I-598.

TEST PRODUCT, BATCH NUMBER, DOSAGE AND MODE OF ADMINISTRATION

Maintenance: Omeprazole 20 mg o.d orally.
Relapse medication: Omeprazole 40 mg o.d orally (2 x omeprazole 20 mg capsules).

Omeprazole 20 mg capsules
Batch Number: H-431-13-2-2, expiry date 30 October 1994
Batch Number: H-431-13-1-11, expiry date 30 September 1995
Batch Number: H-431-13-1-14, expiry date 30 November 1996
Batch Number: H-431-13-1-17, expiry date 01 February 1998
Batch Number: H-431-13-1-19, expiry date 01 November 1998

COMPARATOR PRODUCT, BATCH NUMBER, DOSAGE AND MODE OF ADMINISTRATION

None

DURATION OF TREATMENT

Five years. All patients were discontinued from the extension study at the next 6 monthly visit after a protocol amendment (No. 6) was issued on 02 December 1996.

MAIN VARIABLE(S):

- EFFICACY

  Symptoms: epigastric pain - day and night, heartburn, nausea, vomiting, haematemesis, melaena, endoscopy and biopsy

- SAFETY

  Adverse events

STATISTICAL METHODS

Descriptive methods were used.

PATIENTS

	Omeprazole
No. completed I-598	68
No. entered extension study	63
Males / Females	39/24
No. treated with omeprazole 40 mg o.d for relapse	2
No. discontinued	20
No. reached protocol end-point	34
No. completed	7

SUMMARY

- **EFFICACY RESULTS**

  Four patients relapsed during maintenance treatment with omeprazole 20 mg o.d.

- **SAFETY RESULTS**

  Twenty SAEs, including one death, were reported by 14 patients. Five patients were discontinued from the study due to adverse event. None of the SAEs were considered related to omeprazole therapy.