**Name of company:**
Boehringer Ingelheim

**Name of finished product:**
Gastrozepin

**EudraCT No.:**

**Synopsis No.:**

**Name of active ingredient:**
Pirenzepine

**Page:**
1 of 2

**Module:**

**Volume:**

**Report date:**
16 Dec 1975

**Trial No. / U No.:**
U75-0353

**Date of trial:**
July 1971 – June 1974

**Date of revision (if applicable):**

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**Proprietary confidential information**

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**Title of trial:**
Clinical trial with LS 519 (Pirenzepine)

**Principal/Coordinating Investigator:**
Dr. Tauber

**Trial sites:**
43 sites

**Publication (reference):**
Data of this study has not been published.

**Clinical phase:**
not reported

**Objectives:**
To assess safety and efficacy of pirenzepine

**Methodology:**
two open label parts, followed by two double blind parts

**No. of subjects:**
actual: enrolled: 1424

**Diagnosis and main criteria for inclusion:**
patients with gastric ulcer

**Test product:**
pirenzepine

**dose:**
12.5mg

**mode of admin.:**
1 - 2 tab. x 3 time/day

**batch no.:**
not reported

**Reference therapy:**
placebo in the double blind parts

**dose:**

**mode of admin.:**

**batch no.:**

**Duration of treatment:**
up to 90 days

**Criteria for evaluation:**
Efficacy / clinical pharmacology:
overall assessment by patient and investigator
SUMMARY – CONCLUSIONS:

Efficacy / clinical pharmacology results: Pirenzepine was investigated in 1424 patients, mainly with gastritis, irritable stomach, gastric ulcer, and duodenal ulcer, aged from 17 to 87 years. Apart from the anti-ulcer effect, pirenzepine was also investigated for its effects on appetite and weight, and also for tolerance. The usefulness of this agent was demonstrated in the open label and double blind parts of this study. In the most important indications for ulcer therapy the mean duration of treatment was 21 days. For the assessment by patients /investigators, the therapeutic effect of pirenzepine was assessed as ‘very good’ and ‘good’ in over 80%.

Safety results: Investigators reported 10 adverse events.

Conclusions: The results of these clinical studies have shown that pirenzepine is a substance which fulfils the requirement of an anti-ulcer agent.