**Name of company:** Boehringer Ingelheim

**Name of finished product:** Mexitil

**Name of active ingredient:** Mexiletine

**EudraCT No.:**

**Synopsis No.:**

**Page:** 1 of 2

**Module:**

**Volume:**

**Report date:** 31AUG 1982

**Trial No. / U No.:** U83-0384

**Date of trial:** Not reported

**Date of revision (if applicable):** 11 October 1983

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**Title of trial:** Mexitil vs. Norpace: Multicenter study

**Principal/Coordinating Investigator:** Masood Akhtar

**Trial sites:** Mount Sinai Medical center and other 10 institutes

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

**Clinical phase:** III

**Objectives:** To compare the safety and efficacy of Mexitil with Norpace in the management of ventricular arrhythmias

**Methodology:** Multicentered, double blind, parallel group comparison

**No. of subjects:**

- **actual:**
  - enrolled: 143
  - Treatment Mexitil entered: 74 treated: 74 analysed (for primary endpoint): 74
  - Treatment Norpace entered: 69 treated: 69 analysed (for primary endpoint): 69

**Diagnosis and main criteria for inclusion:** Patients with chronic ventricular arrhythmias with an average of at least 30 PVC’s per hour documented by two 24-hour Holters

**Test product:** Mexiletine

- **dose:** up to 400mg q8h
- **mode of admin.:** po

**Reference therapy:** Norpace

- **dose:** up to 200mg q6h
- **mode of admin.:** po

**Duration of treatment:** 12 weeks

**Criteria for evaluation:**
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**Efficacy / clinical pharmacology:**

24-hour Holter recordings were made in baseline and 12 weeks after treatment. If the PVC rates remained at least 70% below the baselines values, the treatments was evaluated successful suppression. Lab tests, physical exam.

**Safety:**

Adverse events

**Statistical methods:**

descriptive statistics

**SUMMARY – CONCLUSIONS:**

**Efficacy / clinical pharmacology results:**

63 patients in Mexitin group and 54 patients in Norpace group were evaluated of efficacy. 18 patients (28.6%) in Mexitin group and 24 patients (44.4%) in Norpace group showed more than 70 % reduction of PVCs. Norpace had a larger number of treatment success (24/54 patients 44.4%) than did Mexitin (18/63 28.6%).

**Safety results:**

In EKG assessment, no significant difference between the baseline means and the mean at the end of treatment in Mexitin group have been observed. Norpace consistently produced a prolongation of QTc in patients not using Digitalis. Mexitin did not significantly effect visual activity or intraocular pressure.

In Mexitin group, 52 patients had any adverse experiences. Most frequently encountered with Mexitin were upper gastrointestinal distress, light headedness, tremor and coordination difficulties.

The adverse reactions most frequently encountered with Mexitin were upper gastrointestinal distress, Light headedness, tremor and coordination difficulties.

**Conclusions:**

The results of this study do not allow drawing relevant conclusions regarding the use of mexiletine and Norpace in the management of ventricular arrhythmias.