

MEFI/05/DEX-MIG/01

Dexketoprofen Trometamol in the therapy of migraine

This study has completed the enrolment of patients

Sponsor: A. Menarini I.F.R.

Intervention: Dexketoprofen 25mg, Dexketoprofen 50 mg, Placebo

Indication: Migraine

This study is designed to evaluate the efficacy and tolerability of Dexketoprofen in the therapy of migraine

Study type & design: Phase II, single center, randomized, double blind, cross over, placebo-controlled

Main criteria for inclusion:

Diagnosis of mild /moderate migraine, with or without aura according to the 2004 HIS criteria

>18 and < 65 years of age

At least one year migraine history

Age of migraine onset < 50 years of age

Frequency of migraine attacks: at least 2, but no more than 10 for month

Migraine occurring no more than 15days/month

Main criteria for exclusion:

Headache does not fulfil 2004 HIS criteria for migraine

Use of analgesics, anti-inflammatory or drugs for acute treatment of migraine for more than 10 days/months within the last three months

Presence of muscle-skeletal diseases treated with anti-inflammatory/analgesic drugs

Gastric/duodenal ulcer

Moderate/severe renal failure

Severe hepatic failure