

MEFR/05/KET-RHU/001

A phase IV, randomised, double-blind, double-dummy study in two parallel groups KETUM 2,5 gel versus DICLOFENAC 50mg PO in symptomatic osteoarthritis of the hand

This study is currently recruiting patients

Sponsor: Menarini France

Intervention: Ketum 2,5 gel versus Diclofenac 50mg PO

Indication: Osteoarthritis of the hand

This study is designed to compare the symptomatic efficacy and safety of Ketum gel 2.5 mg with diclofenac 50 mg per os in symptomatic osteoarthritis of the hand, with a hypothesis of equivalent efficacy and best safety of ketoprofen gel

Study type & design: phase IV, randomised, double-blind, double-dummy study in two parallel groups

Main criteria for inclusion:

Male or female, outpatients, aged from 45 to 75

With osteoarthritis of the hand or/and arthrosis of the proximal joint of a finger

With acute pain

Fulfilling the American College of Rheumatology criterias

Main criteria for exclusion:

Patient with a secondary osteoarthritis of the hand

Patient with an active pathology of the hand or the superior limb that could interfere with the evaluation of the osteoarthritis of the hand

Patient with a pathology which contraindicates the usage of one or both of the trial treatment

Patient unable to avoid sun or UVA exposure during treatment and 2 weeks following the end of the trial

