

Zeel comp. vs. Diclofenac Summary

Aim:

The purpose of the study was the verification of the efficacy and patient tolerance of Zeel comp. (tablets) administered for osteoarthritis indications.

Methodology:

The efficacy and patient tolerance of Zeel comp. was compared to that of Diclofenac in the context of a randomized, controlled, double-blind study. Both preparations were administered three times daily over a period of 10 weeks (concentration of Diclofenac per tablet = 25 mg) to 125 patients in total. The characterization (anamnesis) of the osteoarthritis was carried out at the beginning of the study by the physician.

The efficacy was determined by the following parameters:

- WOMAC (Western Ontario MacMaster) arthritis index, which is a widely accepted osteoarthritis questionnaire to be filled out by the patient. The scale ranges from 0 (no symptoms) to 10 (very severe symptoms)
- Global assessment (by physician and patient)

The tolerance was determined by the following parameters:

- Global assessment (by physician and patient)
- Undesired events
- Vital parameters
- Laboratory tests (hematology/clinical Chemistry/urine)

Results:

The study demonstrates that the efficacy of Zeel comp, (tablets) in treating mild to moderate gonarthrosis is equivalent to the efficacy of Diclofenac.

Furthermore, the study provided a parallel confirmation of the safety of Zeel comp. (tablets).

This Is the graph you should use for your marketing: The dots represent the mean values and the bars indicate the range into which 95% of all values belong —so the Zeel values lie within the range of the Diclofenac values.

Results of clinical studies are always evaluated by statistical means allowing a certain range —and this statistical analysis leads to the result of equivalent efficacy.

