

## Arnica Gel is as good as any conventional therapy

Summary of the results of the multicentre, randomised, double-blind study to evaluate the **efficacy and safety of topically applied Arnica gel compared to ibuprofen gel** in patients with multiple osteoarthritis of the fingers.

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- Multiple osteoarthritis of the fingers is the third most frequent type of arthritis, after arthritis of the knee and hip
- There are validated scores and international guidelines for the performance of studies of multiple osteoarthritis of the fingers

### How good is the study design?

The study was planned and performed according to strict international guidelines for studies of multiple osteoarthritis of the fingers (OARSI; Osteoarthritis Research Group International) as well as the EMEA guidelines (European Agency for the Evaluation of Medicinal Products) for controlled studies and their statistical evaluation.

**This is virtually the first study to be performed according to these strict guidelines.**

**The study was performed according to GCP rules (Good Clinical Practice).**

### Why use ibuprofen as the reference medication?

- Ibuprofen has been on the market for over 30 years and is one of the most commonly used non steroidal anti-inflammatory drug (NSAID) throughout the world
- In some countries, topical ibuprofen is the market leader among topical NSAIDs

The study was performed from May 2003 to March 2004 (**9 months**). A total of 204 patients were enrolled in the study.

Improvement of both main target parameters, i.e. the pain reduction measured on a 100-mm VAS and the functional capacity of the hands as measured by the Hand Algofunctional Index, had to be achieved for the study to be successful.

**The study was a success because the Arnica gel was found to be equivalent to the ibuprofen gel with regard to both parameters.**

For all secondary target parameters, the Arnica gel achieved the same values as the ibuprofen gel.

- The number of painful joints decreased equally in both groups.
- Morning stiffness diminished equally in both groups.
- The duration of morning stiffness decreased from about 10 minutes to about 5 minutes in both groups.

Considering the patients who assessed efficacy as "very good" or "good", more patients in the Arnica group were satisfied with their gel than in the ibuprofen group.

The investigators also generally evaluated the efficacy of the Arnica gel as better than that of the ibuprofen gel.

89.5% of patients in the Arnica group and 92.9% in the ibuprofen group evaluated tolerability as "very good" or "good".

### Key points

- Arnica gel is as effective as 5% ibuprofen gel (in multiple osteoarthritis of the fingers)
- Arnica gel is equally well tolerated as 5% ibuprofen gel
- Arnica gel is evaluated as more effective by the patients and the doctors
- Equally effective in reducing stiffness and the number of painful joints
- The first multiple osteoarthritis of the fingers study to be performed according to the latest strict international guidelines
- The first Bioforce study comparing a Bioforce product with a synthetic product

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