

Translated from *Biologische Medizin*  
Vol. 29, No. 6, 2000, pp. 295-9

BIOLOGISCHE MEDIZIN

This Journal is regularly listed in EMBASE/Excerpta Medica  
and Complementary Medicine Index (AMED/CATS)

## Osteoarthritis Patients Regain Mobility

### A Double-Blind Study of a Homeopathic Medication

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# Osteoarthritis Patients Regain Mobility

## A Double-Blind Study of a Homeopathic Medication

### Abstract

This double-blind, randomized clinical study utilized the WOMAC Osteoarthritis Index to compare the efficacy of Zeel comp. (tablets) to that of diclofenac in patients with osteoarthritis of the knee. A total of 121 patients from 13 orthopedic practices were admitted to the study. Therapy consisted of either one tablet of Zeel three times a day or one 25-mg tablet of diclofenac three times a day. In both treatment groups, significant and clinically relevant improvements in mobility and functionality of the affected knee joint were noted over the ten weeks of treatment. In addition, patients achieved greater independence and thus also greater self-sufficiency. Therapy with Zeel comp. proved equivalent to treatment with diclofenac.

**Keywords:** Antihomotoxic medicine, clinical study, diclofenac, homeopathy, osteoarthritis, WOMAC, Zeel comp.

### Introduction

Diagnosis of osteoarthritis is based first and foremost on clinical and radiological findings; narrowing of the joint cavity in conjunction with increasing loss of articular cartilage is considered a clear diagnostic sign. In addition to other characteristic radiological findings (osteosclerosis, cysts, changes in the outlines of the affected joint), specific laboratory tests such as synovial fluid analysis may also aid in identification (1).

Definitive diagnosis of osteoarthritis is difficult, however, if radiological changes are not yet evident. Hence, the Osteoarthritis Criteria Subcommittee of the American College of Rheumatology has suggested criteria that permit an algorithmic approach to diagnosing this syndrome (1). This procedure remains unreliable in relating symptom severity and functionality of the affected joint to the extent of radiological findings. Not surprisingly, clinically relevant radiological changes are evident in almost all (>90%) individuals over 40 years of age, while only one-third develop specific symptoms of arthritis (1).

For this reason, evaluations of drug therapies have long included patient self-assessments in the diagnostic process, since the burden of suffering imposed by the underlying illness is determined to a great extent by the patient's personality and individual life circumstances (2). From the patient's perspective, therefore, arthritis-specific symptoms and functional limitations are the foremost considerations in assessing the impact of the illness. Measurement scales such as the WOMAC Osteoarthritis Index and Lequesne's index have been developed to assess the extent

of the arthritis and its effect on the patient's quality of life (3, 4).

The results of the present study were previously published in *Orthopädische Praxis* (5). The purpose of that publication was to present overall changes in the WOMAC Osteoarthritis Index or its three subscales without going into detail (especially in the functionality category).

### A PAIN

How severe is your pain when you are

1. walking on level ground?
2. going up or down stairs?
3. lying in bed at night?
4. sitting or lying down?
5. standing upright?

### B STIFFNESS

How severe is your stiffness

1. immediately after waking up in the morning?
2. after you have been sitting, lying down, or resting later in the day?

### C FUNCTIONALITY

How much difficulty do you have when

1. walking down stairs?
2. climbing stairs?
3. standing up from a sitting position?
4. stand still in an upright position?
5. bending over and touching the floor?
6. walking on level ground?
7. getting in or out of the car?
8. going shopping?
9. putting on socks or stockings?
10. getting up out of bed?
11. taking off socks or stockings?
12. lying in bed?
13. getting into or out of the bathtub?
14. sitting on a chair?
15. sitting down on the toilet/standing up from the toilet?
16. doing strenuous housework?
17. doing light housework?

Tab. 1: WOMAC Osteoarthritis Index (German version)

| WOMAC                   | base value | Reduction after |         |         |          |
|-------------------------|------------|-----------------|---------|---------|----------|
|                         |            | 2 weeks         | 4 weeks | 6 weeks | 10 weeks |
| <b>Total index</b>      |            |                 |         |         |          |
| HOM group (n = 53)      | 5,1        | -0,4            | -0,9    | -1,3    | -1,7     |
| DIC group (n = 61)      | 4,9        | -1,0            | -1,6    | -1,7    | -2,1     |
| Mann-Whitney statistic  |            | 0,36            | 0,41    | 0,46    | 0,46     |
| 90% CR (lower boundary) |            | 0,29            | 0,35    | 0,39    | 0,39     |
| <b>Pain index</b>       |            |                 |         |         |          |
| HOM group (n = 53)      | 4,7        | -0,2            | -0,8    | -1,1    | -1,5     |
| DIC group (n = 61)      | 4,6        | -1,0            | -1,5    | -1,5    | -2,0     |
| Mann-Whitney statistic  |            | 0,38            | 0,44    | 0,47    | 0,45     |
| 90% CR (lower boundary) |            | 0,31            | 0,37    | 0,40    | 0,38     |
| <b>Stiffness Index</b>  |            |                 |         |         |          |
| HOM group (n = 53)      | 5,2        | -0,5            | -1,0    | -1,5    | -2,1     |
| DIC group (n = 61)      | 5,2        | -1,1            | -1,9    | -2,1    | -2,4     |
| Mann-Whitney statistic  |            | 0,43            | 0,41    | 0,46    | 0,47     |
| 90% CR (lower boundary) |            | 0,35            | 0,37    | 0,41    | 0,40     |

Tab. 2: The WOMAC Osteoarthritis Index. Changes in total index and pain and stiffness subindices after 2, 4, 6, and 10 weeks of treatment (arithmetic averages for the per-protocol population,  $p < 0.01$ /Wilcoxon-Pratt test/two-tailed. HOM = Zeel comp., DIC = diclofenac, CR = confidence region)

The purpose of the present paper is to present detailed results of the functionality subscale as they relate to patients' subjective assessment of the therapeutic efficacy of Zeel comp. in comparison to that of diclofenac, one of the most frequent prescribed antirheumatic drugs.

### Methods

The study, conceived as a multi-center, randomized, double-blind clinical test with comparison of parallel groups, was conducted at 13 locations (registered orthopedic practices) in correspondence with German drug law and GCP guidelines. The design of the study included an initial run-in phase during which no antirheumatics or analgesics were allowed other than acetaminophen on an as-needed basis. The subsequent treatment phase consisted of ten weeks of therapy with either one tablet of Zeel comp. three times a day (for the HOM group) or one 25-mg tablet of diclofenac three times a day (for the DIC group). (For details, see (5)). Monitoring examinations conducted after two, four, six, and ten weeks included assessment of arthritis-specific symptoms by means of the WOMAC Osteoarthritis questionnaire (see below).

Zeel comp., manufactured by Biologische Heilmittel Heel GmbH, Baden-Baden, is a homeopathic medication containing the

ingredients Toxicodendron quercifolium e summitatis, Arnica montana, Solanum dulcamara, Sanguinaria canadensis, and sulfur. Studies have confirmed that Zeel comp. is both effective and well tolerated in patients with osteoarthritis of the knee (6, 7). Diclofenac, the drug chosen as the reference substance, is a nonsteroidal antirheumatic drug (NSAID) that has been the subject of many clinical studies; its suitability as a standard of anti-inflammatory and analgesic efficacy has been amply confirmed (2, 8, 9).

To test the efficacy of Zeel comp., arthritic symptoms and joint functions were assessed by means of the WOMAC Osteoarthritis Index, a validated questionnaire for use in patient self-assessment (3, 10). The WOMAC Index, which assesses the progress of osteoarthritis of the knee, consists of 24 questions (divided into three subscales) that cover relevant symptoms and functional limitations in daily life. The first subscale includes five questions about symptoms that cause pain, the second contains two questions about symptoms of stiffness, and the third consists of 17 questions about physical activity and restriction of physical functions (Table 1). Patients answer the questions on a 10 cm-long visual analog scale, with 0 representing no pain or limitation and 10 representing severe pain or limitation. (For details, see (5)).

### Patients

The patients included in the study were diagnosed with mild to moderate osteoarthritis of the knee (ICD-10: M17.9) and had signed a consent form. Patients accepted into the study met the following inclusion criteria:

1. they had suffered from osteoarthritis for at least six months;
2. their diagnosis had been confirmed either clinically or radiologically, according to criteria established by Altman or Kellgren, respectively (11, 12);
3. they had scored at least five and not more than 16 points on Lequesne's index of pain and functionality (4).

Patients with serious hepatic, renal, cardiac, endocrine, and/or hematological diseases, asthma, or chronic obstructive pulmonary disease were not admitted to the study. With the exception of acetaminophen on an as-needed basis, concomitant therapy with other antirheumatics/analgesics, muscle relaxants, anticoagulants, or anti-ulcer medications was not permitted during the study (for details, see (5)).

### Results

#### Efficacy

In total, 125 patients with osteoarthritis of the knee (62 in the HOM group and 63 in the DIC group) were admitted to the study. Four patients were excluded during the run-in phase (not randomized); three already taking the test medication were excluded from the intent-to-treat population; and four additional patients were excluded from the per protocol population, leaving a total of 53 patients in the HOM group and 61 patients in the DIC group. These two treatment groups were demographically and anamnesticly comparable when the study began (for details, see (5)). In the course of the ten-week treatment, clinical and significant declines in both the overall WOMAC Index and its pain and stiffness subindices were recorded in both groups in comparison to the base values; improvement after six weeks of therapy was comparable in the two groups (for details, see (5)) (Table 2).

At commencement of therapy, the groups were also comparable with regard to scores on the WOMAC function index, which measures the physical functional ability of the affected knee joint in terms of 17 items relating especially to difficulties in caring for oneself in daily life. Situations in which the affected knee clearly impairs or at least limits mobility correspond to the cardinal symptoms of osteoarthritis. Experience indicates that the activities "going up or down stairs" "bending over and touching the floor" and "doing strenuous housework" generally cause the most pain, and correspondingly high base values (6.0 to 7.0) were recorded for functional impairment during these activities. The changes in these symptoms were also the greatest, ranging from -2.0 to -2.7. The patients reported additional functional limitations in situations requiring good mobility and balance, such as "getting into/out from the car/bathtub", "getting out of bed", and "standing up from a sitting position." To summarize the results of therapy, significant improvement in the functionality of the affected knee joint occurred with respect to all 17 items in the course of the ten weeks of treatment. At the latest, equivalence was established between the two groups after six weeks (Table 3).

**Discussion**

Since there is as yet no treatment for the cause of osteoarthritis, pharmaceutical therapy consists first and foremost of treating the clinical symptoms. In clinical studies conducted to prove the efficacy of specific forms of therapy, assessment criteria generally consist of subjective observations on the impact of the illness and the medication's effect on pain (1). NSAIDs, considered the therapeutic standard by some working groups, are frequently prescribed for osteoarthritis (13). While the purpose of therapeutic use of NSAIDs is to relieve pain, preserve mobility, and minimize functional impairment, this therapy can have damaging adverse effects (primarily on the gastrointestinal tract) (14, 15). Therefore patients' assessment of their own state of health is very important in evaluating any therapy. The often sudden

| WOMAC questions from the functionality subindex | base value | Reduction after |         |         |          |
|---|------------|-----------------|---------|---------|----------|
|   |            | 2 weeks         | 4 weeks | 6 weeks | 10 weeks |
| <b>Total subindex</b>                           |            |                 |         |         |          |
| HOM group                                       | 5,2        | -0,4            | -1,0    | -1,4    | -1,7     |
| DIC group                                       | 4,9        | -0,9            | -1,5    | -1,6    | -2,0     |
| Mann-Whitney statistic                          |            | 0,42            | 0,43    | 0,48    | 0,46     |
| 90% CR (lower boundary)                         |            | 0,35            | 0,37    | 0,41    | 0,40     |
| <b>Walking down stairs</b>                      |            |                 |         |         |          |
| HOM group                                       | 5,9        | -0,2            | -1,1    | -1,5    | -2,0     |
| DIC group                                       | 6,2        | -1,2            | -1,8    | -1,9    | -2,4     |
| Mann-Whitney statistic                          |            | 0,44            | 0,45    | 0,48    | 0,49     |
| 90% CR (lower boundary)                         |            | 0,38            | 0,39    | 0,41    | 0,42     |
| <b>Walking up stairs</b>                        |            |                 |         |         |          |
| HOM group                                       | 6,0        | -0,6            | -1,3    | -1,7    | -2,1     |
| DIC group                                       | 5,7        | -1,3            | -1,9    | -1,5    | -2,1     |
| Mann-Whitney statistic                          |            | 0,44            | 0,44    | 0,53    | 0,52     |
| 90% CR (lower boundary)                         |            | 0,37            | 0,37    | 0,46    | 0,45     |
| <b>Getting up from a sitting position</b>       |            |                 |         |         |          |
| HOM group                                       | 5,5        | -0,2            | -0,8    | -1,3    | -1,8     |
| DIC group                                       | 5,4        | -1,0            | -1,6    | -1,8    | -2,3     |
| Mann-Whitney statistic                          |            | 0,38            | 0,43    | 0,47    | 0,46     |
| 90% CR (lower boundary)                         |            | 0,31            | 0,36    | 0,40    | 0,39     |
| <b>Standing</b>                                 |            |                 |         |         |          |
| HOM group                                       | 5,5        | -0,7            | -1,4    | -1,7    | -2,0     |
| DIC group                                       | 4,6        | -0,6            | -1,3    | -1,3    | -1,8     |
| Mann-Whitney statistic                          |            | 0,48            | 0,52    | 0,57    | 0,52     |
| 90% CR (lower boundary)                         |            | 0,41            | 0,45    | 0,50    | 0,45     |
| <b>Bending over to touch the floor</b>          |            |                 |         |         |          |
| HOM group                                       | 6,2        | -0,8            | -1,3    | -2,1    | -2,0     |
| DIC group                                       | 6,0        | -1,1            | -1,9    | -2,3    | -2,5     |
| Mann-Whitney statistic                          |            | 0,43            | 0,43    | 0,47    | 0,47     |
| 90% CR (lower boundary)                         |            | 0,36            | 0,36    | 0,40    | 0,40     |
| <b>Walking on level ground</b>                  |            |                 |         |         |          |
| HOM group                                       | 4,2        | -0,1            | -0,6    | -0,9    | -1,0     |
| DIC group                                       | 3,8        | -0,3            | -1,1    | -1,1    | -1,3     |
| Mann-Whitney statistic                          |            | 0,41            | 0,41    | 0,44    | 0,44     |
| 90% CR (lower boundary)                         |            | 0,34            | 0,34    | 0,37    | 0,38     |
| <b>Getting into/out of the car</b>              |            |                 |         |         |          |
| HOM group                                       | 5,5        | -0,2            | -0,8    | -1,1    | -1,6     |
| DIC group                                       | 5,9        | -1,5            | -1,9    | -2,1    | -2,6     |
| Mann-Whitney statistic                          |            | 0,34            | 0,39    | 0,42    | 0,40     |
| 90% CR (lower boundary)                         |            | 0,27            | 0,32    | 0,35    | 0,33     |
| <b>Going shopping</b>                           |            |                 |         |         |          |
| HOM group                                       | 5,3        | -0,9            | -1,5    | -1,6    | -1,9     |
| DIC group                                       | 4,8        | -0,7            | -1,6    | -1,6    | -2,1     |
| Mann-Whitney statistic                          |            | 0,49            | 0,46    | 0,48    | 0,45     |
| 90% CR (lower boundary)                         |            | 0,42            | 0,39    | 0,42    | 0,38     |

Tab. 3: The WOMAC functionality index. Changes after 2, 4, 6, and 10 weeks of treatment (arithmetic average for the per-protocol population, p < 0.01 Wilcoxon-Pratt test/two-tailed. HOM = Zeel comp., DIC = diclofenac, Mann-Whitney statistic = average value, CR = confidence region)

appearance of severe pain can cause patients to avoid physical exertion and withdraw from important daily social activities. Thus one of the purposes of therapeutic measures is to reduce both the number and the severity of pain episodes in order to restore mobility and functionality in everyday life.

With the help of the WOMAC questionnaire, the present equivalence study proves that both therapy with Zeel comp. and treatment with diclofenac achieve significant decreases in typical arthritis symptoms. After six weeks of treatment, the two groups were equivalent not only in terms of the total WOMAC Osteoarthritis

| WOMAC questions from the functionality subindex        | base value | Reduction after |         |         |          |
|--|------------|-----------------|---------|---------|----------|
|  |            | 2 weeks         | 4 weeks | 6 weeks | 10 weeks |
| <b>Putting on socks/stockings</b>                      |            |                 |         |         |          |
| HOM group  | 4,9        | -0,6            | -0,7    | -0,9    | -1,6     |
| DIC group  | 5,2        | -1,2            | -1,6    | -1,9    | -2,1     |
| Mann-Whitney statistic                                 |            | 0,47            | 0,41    | 0,39    | 0,44     |
| 90% CR (lower boundary)                                |            | 0,40            | 0,34    | 0,33    | 0,37     |
| <b>Getting out of bed</b>                              |            |                 |         |         |          |
| HOM group  | 5,4        | -0,7            | -1,4    | -2,0    | -2,0     |
| DIC group  | 5,1        | -1,3            | -1,7    | -1,9    | -2,2     |
| Mann-Whitney statistic                                 |            | 0,44            | 0,49    | 0,52    | 0,50     |
| 90% CR (lower boundary)                                |            | 0,37            | 0,43    | 0,45    | 0,43     |
| <b>Taking off socks/stockings</b>                      |            |                 |         |         |          |
| HOM group  | 4,7        | -0,5            | -0,6    | -0,9    | -1,5     |
| DIC group  | 4,7        | -1,1            | -1,3    | -1,6    | -1,9     |
| Mann-Whitney statistic                                 |            | 0,42            | 0,40    | 0,38    | 0,43     |
| 90% CR (lower boundary)                                |            | 0,35            | 0,34    | 0,31    | 0,36     |
| <b>Lying in bed</b>                                    |            |                 |         |         |          |
| HOM group  | 4,2        | -0,4            | -0,7    | -1,2    | -1,5     |
| DIC group  | 3,5        | -0,6            | -1,1    | -1,1    | -1,1     |
| Mann-Whitney statistic                                 |            | 0,48            | 0,47    | 0,52    | 0,54     |
| 90% CR (lower boundary)                                |            | 0,41            | 0,40    | 0,45    | 0,47     |
| <b>Getting into/out of the bathtub</b>                 |            |                 |         |         |          |
| HOM group  | 5,6        | -0,5            | -0,9    | -1,3    | -1,6     |
| steigenDIC group                                       | 5,9        | -1,2            | -1,8    | -2,0    | -2,5     |
| Mann-Whitney statistic                                 |            | 0,40            | 0,37    | 0,44    | 0,42     |
| 90% CR (lower boundary)                                |            | 0,33            | 0,30    | 0,37    | 0,35     |
| <b>Sitting</b>   |            |                 |         |         |          |
| HOM group  | 3,9        | -0,2            | -0,6    | -0,8    | -1,1     |
| DIC group  | 3,6        | -0,4            | -1,0    | -1,1    | -1,5     |
| Mann-Whitney statistic                                 |            | 0,40            | 0,42    | 0,44    | 0,45     |
| 90% CR (lower boundary)                                |            | 0,33            | 0,35    | 0,37    | 0,38     |
| <b>Sitting down on or getting up off of the toilet</b> |            |                 |         |         |          |
| HOM group  | 4,3        | -0,4            | -0,7    | -1,1    | -1,2     |
| DIC group  | 3,5        | -0,1            | -0,7    | -0,9    | -1,1     |
| Mann-Whitney statistic                                 |            | 0,51            | 0,51    | 0,51    | 0,52     |
| 90% CR (lower boundary)                                |            | 0,44            | 0,44    | 0,44    | 0,45     |
| <b>Strenuous housework</b>                             |            |                 |         |         |          |
| HOM group  | 7,0        | -0,7            | -1,8    | -2,2    | -2,4     |
| DIC group  | 6,5        | -1,3            | -2,0    | -2,1    | -2,7     |
| Mann-Whitney statistic                                 |            | 0,38            | 0,46    | 0,52    | 0,48     |
| 90% CR (lower boundary)                                |            | 0,31            | 0,39    | 0,46    | 0,41     |
| <b>Light housework</b>                                 |            |                 |         |         |          |
| HOM group  | 4,4        | -0,4            | -0,9    | -0,9    | -1,3     |
| DIC group  | 3,8        | -0,5            | -0,8    | -1,1    | -1,5     |
| Mann-Whitney statistic                                 |            | 0,46            | 0,53    | 0,48    | 0,50     |
| 90% CR (lower boundary)                                |            | 0,39            | 0,46    | 0,41    | 0,43     |

Tab. 3, continued

tis Index but also in the subindices measuring pain, stiffness, and functionality. Changes in both the total index and the three subindices were comparable to the results of other WOMAC-based studies of NSAIDs (e.g., tenoxicam, diclofenac) (2, 8).

The WOMAC osteoarthritis questionnaire is an illness-specific instrument for assess-

ing painful symptoms and functional impairment of the affected knee joint (3). In series of tests on patients, the validated German version of the original Anglo-American instrument performed well in terms of its scale structure and reliability, and the function scale correlated most clearly with extension deficits, the extent of radiological changes, and the degree of

restriction of flexion of the knee joint (10). Earlier studies evaluating the WOMAC Osteoarthritis Index had already indicated clear correlations with psychosocial variables such as degree of impairment during daily activities at home and at work and social integration into one's family and circle of acquaintances (2, 3).

In summary, on the basis of the results of the present study, it is safe to state that therapy with Zeel comp. (tablets) for mild to moderate osteoarthritis of the knee produces clear improvements in mobility and functionality and reduces the burden of pain. These improvements are associated with enhanced quality of life for the patients. In this respect, Zeel comp. therapy is equivalent to treatment with the NSAID diclofenac.

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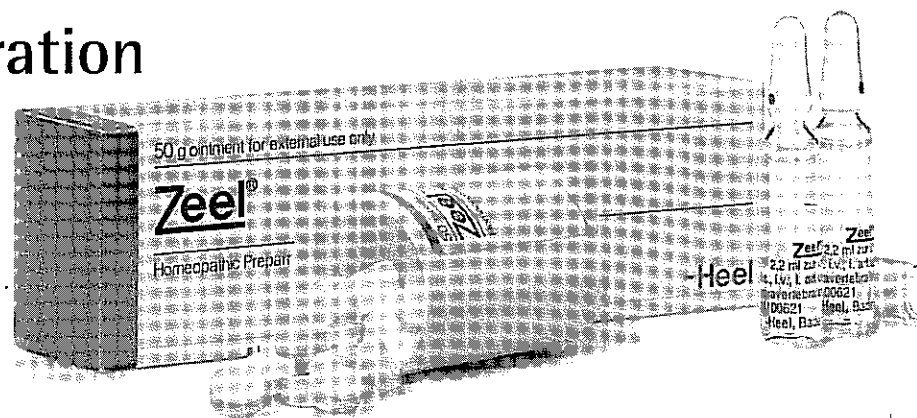
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# Zeel®

## The Homeopathic Alternative

- ➔ Arthritic degeneration
- ➔ Stiffness
- ➔ Pain



**Composition:** Injection Solution: 2.2 ml cont.: Extr. (1:10) of *Cartilago suis*, extr. (1:10) of *Funiculus umbilicalis suis*, extr. (1:10) of *Embryo suis*, extr. (1:10) of *Placenta suis* 22 ng each; *Rhus toxicodendron D*, *Arnica D* 0.22 mg each; *Dulcamara D*, *Symphylum D* 22 µg each; *Sanguinaria D* 33 µg; *Sulfur D (=D4)* 39.6 µg; *Nadidum*, *Coenzym A*, *Acidum alpha-liponicum*, *Natrium diethylxalacetatum* 0.22 ng each. Tablets: 1 tablet cont.: Extr. (1:10) of *Cartilago suis*, extr. (1:10) of *Funiculus umbilicalis suis*, extr. (1:10) of *Embryo suis*, extr. (1:10) of *Placenta suis* 0.3 µg each; *Rhus toxicodendron D* 0.106 mg, extr. flor. *Arnicae* (spir. fid. 1:1) 0.06 mg; *Dulcamara D* 3 µg; *Symphylum D* 0.93 µg; *Sanguinaria D* 4.5 µg; *Sulfur D* 5.4 µg; *Acidum silicicum colloidalis* 3 ng; *Nadidum*, *Coenzym A*, *Acidum alpha-liponicum*, *Natrium diethylxalacetatum* 0.03 ng each. Ointment: 100 g cont.: *Cartilago suis D2*, *Funiculus umbilicalis suis D2*, *Embryo suis D2*, *Placenta suis D2* 0.001g each; *Rhus toxicodendron D2* 0.270 g; *Arnica montana D2* 0.300 g; *Solanum dulcamara D2* 0.075 g; *Symphylum D8* 0.750 g; *Sanguinaria canadensis D2* 0.225 g; *Sulfur D6* 0.270 g; *Nadidum D6*, *Coenzym A D6*, *Acidum alpha-liponicum D6*, *Natrium diethylxalacetatum D6* 0.010 g each; *Acidum silicicum D6* 1.000 g. Ointment base: Hydrophilic ointment containing emulsifying cetylstearyl alcohol, ethanol, purified water, viscous paraffin, white vaseline, preserved with 12.9 vol.-% ethanol.

**Indications:** Arthritic degeneration (particularly of the knee), polyarthrosis, spondylarthrosis, scapulohumeral periarthrosis. **Contraindications:** Injection Solution, Tablets: Hypersensitivity to botanicals of the Compositae family or the genus *Rhus* of the Anacardiaceae family. Ointment: Hypersensitivity to arnica, the genus *Rhus* of the Anacardiaceae family and constituents of the ointment base. **Side effects:** Ointment: In rare cases, allergic skin reactions may occur.

## -Heel

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