A Randomized, Double-Blind, Phase III Trial in Moderate Osteoarthritis Knee Pain Comparing Topical Ketoprofen in Transfersome Gel with Ketoprofen-Free Gel.

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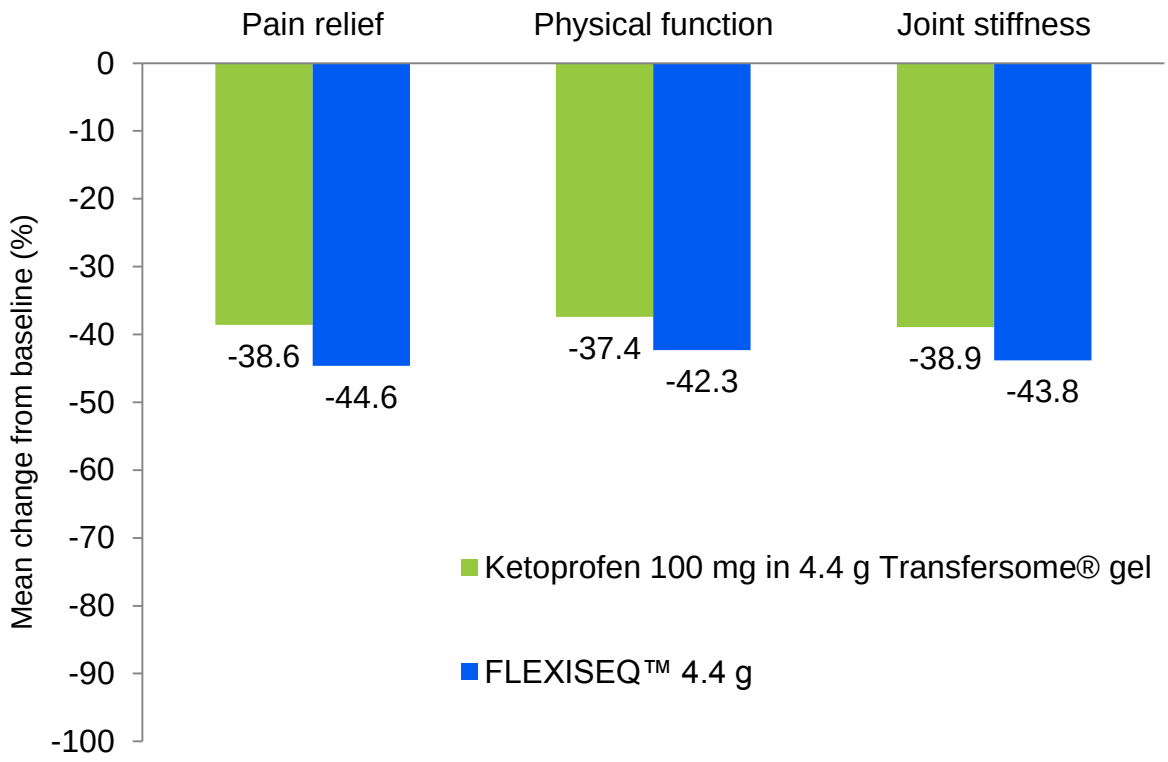
Summary

We are pleased to provide you with a summary of a key paper recently published in the Journal of Rheumatology. This study (CL-033-III-06) compared the use of FLEXISEQ™ (TDT 064), the drug-free Sequessome™ treatment for the pain and stiffness of OA, with a ketoprofen carrying Transfersome® preparation (IDEA 033). 555 patients with moderate OA-associated knee pain were enrolled and treated twice daily for 12 weeks.

As is standard for OA clinical trials, study III-06 assessed pain, function and stiffness in the knee joint using the Western Ontario and McMaster Universities Arthritis Index (WOMAC). Patients treated with FLEXISEQ™ showed progressive and clinically relevant improvements in the WOMAC subscales for pain, function, and stiffness which were statistically greater than the improvements seen for the ketoprofen in Transfersome® treated patients. Mean change in WOMAC pain scores from baseline to Week 12 was 44.6% for FLEXISEQ® compared to 38.6% for the ketoprofen in Transfersome® arm. Likewise, mean baseline WOMAC function scores decreased from 5.4 to 3.1 with FLEXISEQ® and to 3.4 with ketoprofen in Transfersome® at Week 12.

50.5% of patients treated with FLEXISEQ® achieved ≥ 50% decrease in WOMAC pain score from baseline at Week 12 (compared to 41.2% for the ketoprofen in Transfersome® arm.

The graph below shows the mean change from baseline in, respectively, VAS WOMAC Pain, Function and Stiffness Subscale scores from baseline to Week 12 (ITT population)



FLEXISEQ™ was well tolerated by the patients in this study. The majority of the AEs reported with FLEXISEQ™ were local skin reactions (reported in 11.4% patients treated with FLEXISEQ™). There were no serious treatment-related AEs reported.

This paper further substantiates the beneficial effects of FLEXISEQ™ in the treatment of the symptoms of OA. The authors comment that the findings were comparable to those published in Rheumatology earlier this year where FLEXISEQ™ was found to have comparable efficacy to oral celecoxib.

The full text of this paper can be accessed:

http://jrheum.org/content/40/10/1742.full.

Further publications of the clinical programme of FLEXISEQ™ studies are ongoing.

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