SUMMARY: The efficacy of a novel, proprietary topical formulation of ibuprofen 5% gel (Ibugel™) was evaluated in a placebo-controlled study in patients with soft tissue injuries. Patients received either active gel (n=40) or placebo gel (n=41) for a maximum of seven days. Pain and interference with physical activity were assessed daily using visual analogue scales. There was a significant difference ($p<0.001$) in favour of active treatment for the time to achieve clinically meaningful reduction in pain. By day 7, 75% of patients in the active gel group had a clinically meaningful reduction of pain compared with 39% of patients who received placebo. Despite differences between study centres, the data for interference with physical activity also showed an advantage for active treatment. By day 7, 79% of patients in the active gel group had a clinically meaningful reduction in interference with physical activity, compared with 44% of patients who received placebo.