

# **Analgesic effect of topical piroxicam versus phytotherapy gel in the treatment of acute soft tissues injuries: a randomized controlled non-inferiority study**

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## **Abstract**

**Objective:** The study compared the efficacy and tolerability of piroxicam gel and a new topical combination of medicinal plant products (Soulagel®) to treat pain caused by soft tissue injuries.

**Methods:** 1525 patients were assigned to receive piroxicam gel or Soulagel®. Efficacy assessments included pain-on-movement (POM) VNS (visual numeric scale) change from emergency department (ED) discharge (baseline) by at least 50% at day-7 final assessment, the time required to reach pain resolution criteria, need for rescue analgesia, patients' satisfaction, and rate of adverse effects.

**Results:** At day-7, 1216 patients (79.7%) achieved at least 50% reduction of VNS from baseline; 623 patients (82.4%) in Soulagel® group vs. 593 patients (77.1%) in piroxicam group ( $p = 0.01$ ). Time to decrease POM by 50% was significantly higher with piroxicam gel compared to Soulagel® ( $34 \pm 1$  vs  $33 \pm 1$  days respectively;  $p = 0.54$ ). At day 7, 96.4% of patients in Soulagel® group declared being "very satisfied" to "satisfied" vs. 68% in piroxicam group ( $p < 0.001$ ). There was no major adverse events in both groups.

**Conclusion:** Soulagel® is not inferior to piroxicam gel for managing pain related to a soft tissues injuries. Further studies will help ascertain whether this new gel offers an alternative treatment option in this common ED condition.

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