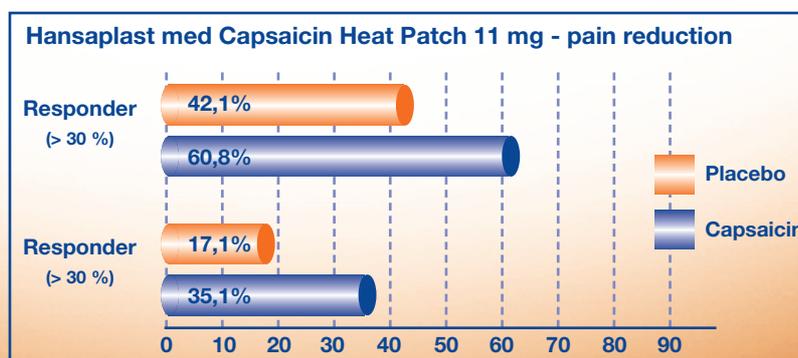


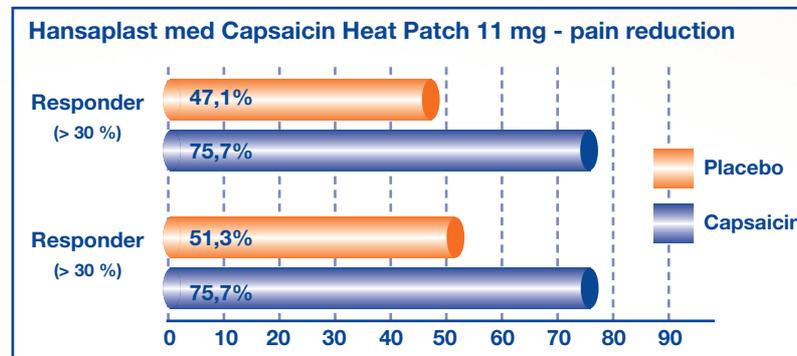
Hansaplast med Capsaicin Heat Patch 11 mg

Study title:	Capsicum pain plaster in chronic non-specific low back pain.
Author:	Keitel W ^a , Frerick H ^b , Kuhn U ^b , Schmidt S ^b , Kuhlmann M ^c , Bredehorst A ^c
Source:	Arzneim-Forsch./Drug Res. 51 (II), 896-903 (2001) <small>^a Klinik für Rheumatologie, Gommerna ^b AFA, Arbeits- und Forschungsgemeinschaft für Arzneimittel, Köln ^c Scientific and Regulatory Affairs, Beiersdorf AG, Hamburg</small>
Test Product:	Capsicum Pain Plaster 11 mg, Placebo Plaster
Study objective:	Efficacy and safety of a capsicum plaster in comparison with a placebo in patients with chronic pain of the dorsal muscles.
Method:	Randomized, placebo-controlled, double-blind, parallel-group comparison
Participants:	154 subjects, (placebo = 77 patients, active ingredient = 77 patients)
Diagnosis:	Back pain at rest and during exercise of at least three months' duration Severity of subjective pain of at least 5 (on an 11-point pain scale)
Duration:	Three weeks
Application time:	4-12 hours daily to the painful area

Results: **Efficacy**
 For patients to be rated as responders, their total pain score had to show a reduction by at least 30% over the baseline value. The study unequivocally achieved the target criterion with a rate of responders in the capsicum group of 60.8% against 42.1% in the placebo group. 35.1% of subjects in the capsicum group reported pain reduction of more than 50%, twice as many as in the placebo group (17.1%).



The efficacy ratings by observers and patients were also definitely in favour of capsicum. The assessment of “excellent” or “good”, respectively “free from symptoms” or “improved”, was entered by 75.7% of physicians and 75.7% of patients.



Results:

Safety and local tolerability

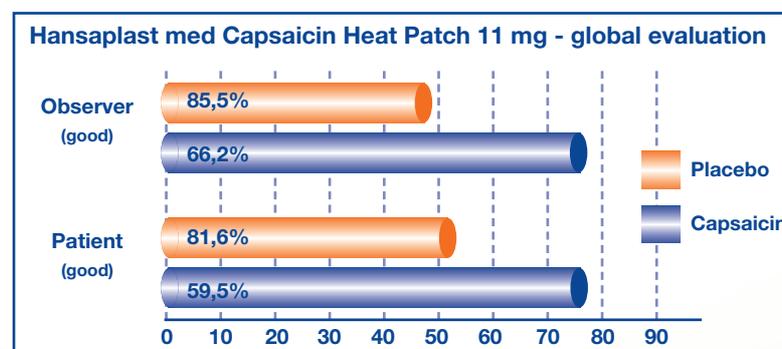
Adverse events, mostly categorized as not severe, were reported by 15 patients in the capsicum group and 9 patients in the placebo group.

The predominant symptoms reported for capsicum were sensation of heat or erythema of varying severity.

The sensation of warmth and erythema is part of the normal pharmacological action of capsaicin and patients can differ widely in their individual tolerance of these effects.

The global evaluation of tolerance by investigators and patients favoured the placebo.

The physicians rated the tolerance of the capsicum and the placebo treatment as good in 66.2 % and 85.5 % of the cases. The corresponding ratings by patients were 59.5% and 81.6%.



Conclusion

The study shows significant efficacy of the Capsicum Pain Plaster 11 mg over a placebo plaster in chronic non-specific back pain. The lack of systemic side effects and the easy handling of the plaster formulation support the risk-benefit ratio of this product. Capsicum Pain Plaster 11 mg offers a genuine alternative in the treatment of non-specific low back pain.