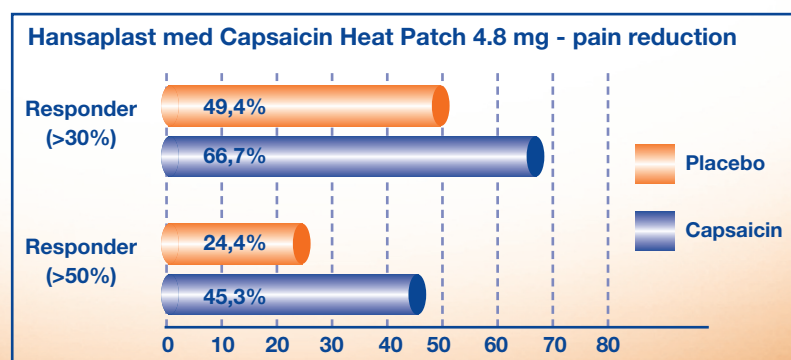
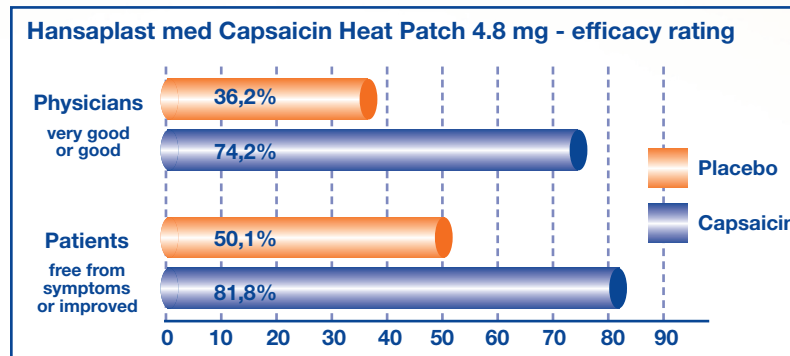


Hansaplast med Capsaicin Heat Patch 4.8 mg

| | |
|--------------------------|--|
| Study title: | Topical treatment of chronic low back pain with a capsicum plaster. |
| Author: | Frerick H ^a , Keitel W ^b , Kuhn U ^a , Schmidt S ^a , Bredehorst A ^c , Kuhlmann M ^c |
| Source: | Pain. 2003 Nov; 106(1-2):59-64 <small>^a AFA, Arbeits- und Forschungsgemeinschaft für Arzneimittel, Köln ^b Klinik für Rheumatologie, Gommern ^c Scientific and Regulatory Affairs, Beiersdorf AG, Hamburg</small> |
| Test Product: | Capsicum Pain Plaster 4.8 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: | 320 subjects, (placebo = 160 patients, active ingredient = 160 patients)n |
| 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: | 4-8 hours daily to the painful area |
| Results: | 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 67% against 49% in the placebo group. 45% of subjects in the capsicum group reported pain reduction of more than 50%, nearly twice as many as in the placebo group (24%). |



The efficacy ratings by observers and patients were also definitely in favour of capsaicin. The assessment of “excellent” or “good”, respectively “free from symptoms” or “improved”, was entered by 74.2% of physicians and 81.8% of patients.



Results:

Safety and local tolerability

Adverse events, mostly categorized as not severe, were reported by 18 patients in the capsaicin group and 8 patients in the placebo group.

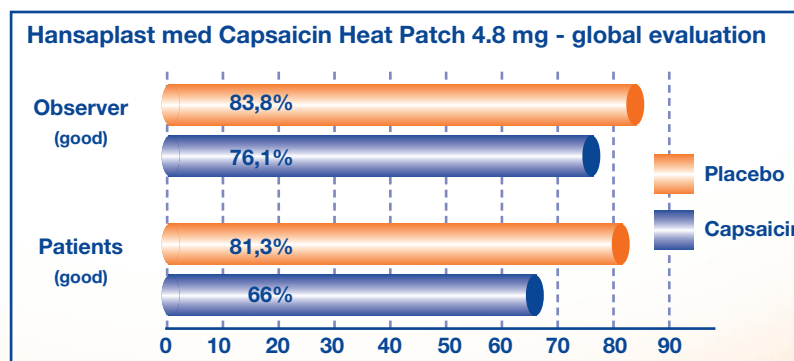
The predominant symptoms reported for capsaicin were sensation of heat or erythema of varying severity.

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

Only 9 patients in the Capsaicin group showed local sensitivity to the preparation.

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

The physicians rated the tolerance of the capsaicin and the placebo treatment as good in 76.1% and 83.8% of the cases. The corresponding ratings by the patients were 66.0% and 81.3%.



Conclusion

The study shows significant efficacy of the Capsaicin Pain Plaster 4.8 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.

Capsaicin Pain Plaster 4.8 mg offers a genuine alternative in the treatment of non-specific low back pain.