

## Evidence-based therapy with Traumaplant®:

- Four of these studies are double-blind, randomised and controlled: Each study included up to 300 patients.
- All results are statistically significant and correspond to the current status of the internationally recognized study guidelines.
- Some of the study results (wound healing, use in children) show a real superiority over high-volume chemical and herbal competitors (e.g. Diclofenac).
- The scientific study material may be used by licensees both for registration and marketing purposes.

Author	Indication	Duration of study	Therapeutical effect
KUCERA et al(2018)	Tolerability and effectiveness in pediatric use with application on intact and on broken skin	14 days	<p>A total of 712 children (386 children with intact skin and 326 children with abrasions and superficial wounds) were openly treated with 1-5 applications daily after presenting for blunt traumas and sports accidents.</p> <p>No adverse events occurred in the group of children with intact skin, and one intolerance reaction (burning and reddening) was observed after application to broken skin.</p> <p>This study confirms an excellent benefit-to-risk ratio for the application of comfrey herb cream in the treatment of blunt traumas and sports injuries in children with intact and with broken skin.</p>
UEBELHACK et al(2014)	Muscle pain related to overload-induced muscle soreness	1-2 days per patient	<p>Symptoms of muscle soreness were induced in 24 healthy persons by a standardised muscle overload of both upper arms under controlled conditions. In the evaluation of the responder rate a significant effect was observed for pain on pressure already after 30 and 120 minutes. An improvement of pain on movement was already shown in the comparison of groups after 15 minutes.</p>
KUCERA et al(2012)	Acute and chronic back pain	8 -10 days	<p>The efficacy and tolerability of a topical preparation with an active substance concentrate made from the aerial parts of medicinal comfrey (<i>Symphytum x uplandicum</i> NYMAN) was tested in 215 patients with acute or chronic myalgia of the upper and lower back.</p>

			Conclusion: Topical comfrey extract has a fast acting analgesic effect in myalgia of the back caused by chronic strain as well as acute blunt injury.
BARNA et al(2012) *	Wound healing in children	7 -9 days	In this double-blind, randomized, parallel clinical trial in 108 children (3-12 years) with fresh superficial skin abrasions Traumaplant reduced the wound area to 50% approx. one day quicker than the reference product (1% Symphytum extract). Efficacy, excellent safety and tolerability of Traumaplant in the indication acceleration of wound healing in children could be demonstrated.
Schmidt et al (2011)	Children with acute, blunt traumata	7 days	The results of this non-interventional study regarding the tolerability and effectiveness of the medication are consistent with previously published clinical data in adults. 361 male and female children in the age of 4–12 years with acute blunt traumata (contusions, strains or distortions which occurred within the last 48 hours) were examined in 8 German centres in the years 2008 and 2010. This product, which combines anti-inflammatory and analgesic effects in a topical preparation, offers a safe and effective approach.
Guth, A(2009)	Functional disorders of the cervical vertebral column	3 weeks	In a study realized in two rehabilitation clinics with 255 patients having the cervical syndrome the test persons additionally applying Traumaplant® experienced a significantly or numerically more pronounced relaxation of contracted muscles (especially the trapezius muscle) as well an improved mobility of muscle fasciae.
Barna et al.(2007) *	Wound healing	10 days	Distinct wound healing effects can be attributed to Traumaplant as a result of a randomized, double-blind study with 278 patients. The results can explicitly also be made use for the administration of children. The product in a 10% dosage of active ingredient was tested against a reference cream containing 1% of active ingredient.
Kucera, M.(2005) *	Muscle pain (Myalgia)	10 days	In a double-blind randomised and controlled clinical trial with 218 patients the local efficacy and safety of Symphytum herb extract ointment 10% against 1% in the indication muscle pain – myalgia could be confirmed. Compared to reference product, the active

			treatment was clearly superior regarding the reduction of the primary criterion pain on active motion
Kucera, M.(2004)*	Accidental and sports injuries (Ankle distortion)	14 days	In a double-blind randomised clinical trial (203 patients) the efficacy, safety and tolerability as well as the excellent risk-benefit ratio of Traumaplant® cream with accidental and sports injuries (ankle distortion) could be demonstrated.
Kucera, M.(2000)	Muscular Symptoms and Functional Disturbances	14 days	In an open uncontrolled study, 105 patients with locomotor system symptoms were treated twice daily. A clear therapeutic effect was noted on chronic and subacute symptoms that were accompanied mainly by functional disturbances and pain in the musculature. The preparation was most effective against muscle pain, swelling and overstrain, arthralgia/distortions, enthesopathy and vertebral syndrome.
Mayer, G.(1993)	Acute Supraspinatus Tendon Syndrome (Painful shoulder)	21 days	Comparative study (30 patients during 3 weeks) between test group (Traumaplant®) and control group (without the additional topical treatment): Significantly better efficacy of test group i.e. pain symptoms and correlated functional disturbances decreased considerably. The clinical criteria were day pain, night pain and "abduction-provoked painful arc".
Mayer, G.(1992)	Contusions and Distortions of the Knee Joint	14 days	The local efficacy of a phyto-antitraumatic (an ointment containing a Symphytum active substance complex) was tested with acute contusions and distortions of the knee joint. Clinical symptoms (joint swelling, pain on active and passive movement, local rest pain) decreased rapidly and soon subsided. All 22 investigated patients were completely free of pain after 10 to 14 days or even earlier.
Hess, H.(1991)	Sports Injuries of the Knee Joint	8 days	Treatment with a Symphytum peregrinum ointment was carried out for an average of 8 days on 40 patients suffering from recent knee joint injuries, distortions and contusions which did not require surgery. 85% of the patients rated the efficacy of the preparation as good to very good in case of blunt sports injuries (Criteria for the therapeutical effect were pain, swelling and limitations of moving)

Mayer, G.(1991)	Acute lateral Distortions of the Ankle Joint	14 days	Significantly positive result with Traumaplast® compared with conventional cryotherapy. The clinical criteria of this controlled study are resting pain, pain on movement and swelling (Tested no. of patients: 28)
Niedner, R. (1989)	Open shallow wounds	5 days	Significant effect on the stimulation of epithelialization in the case of open shallow wounds with an intact columnar layer in healthy volunteers (10 patients). The ointment base and a polyacrylamide agar gel with active substances served as controls.