WORLD-CLASS TREATMENT IN MUSCULOSKELETAL INJURIES

Traumeel®

TRAUMEEL® - LATEST RESEARCH IS AVAILABLE ON INFLAMMATION RESOLUTION AND TISSUE HEALING [1,2]

TRAUMEEL® DEMONSTRATES A POTENTIAL MECHANISM OF ACTION THAT DIFFERS...

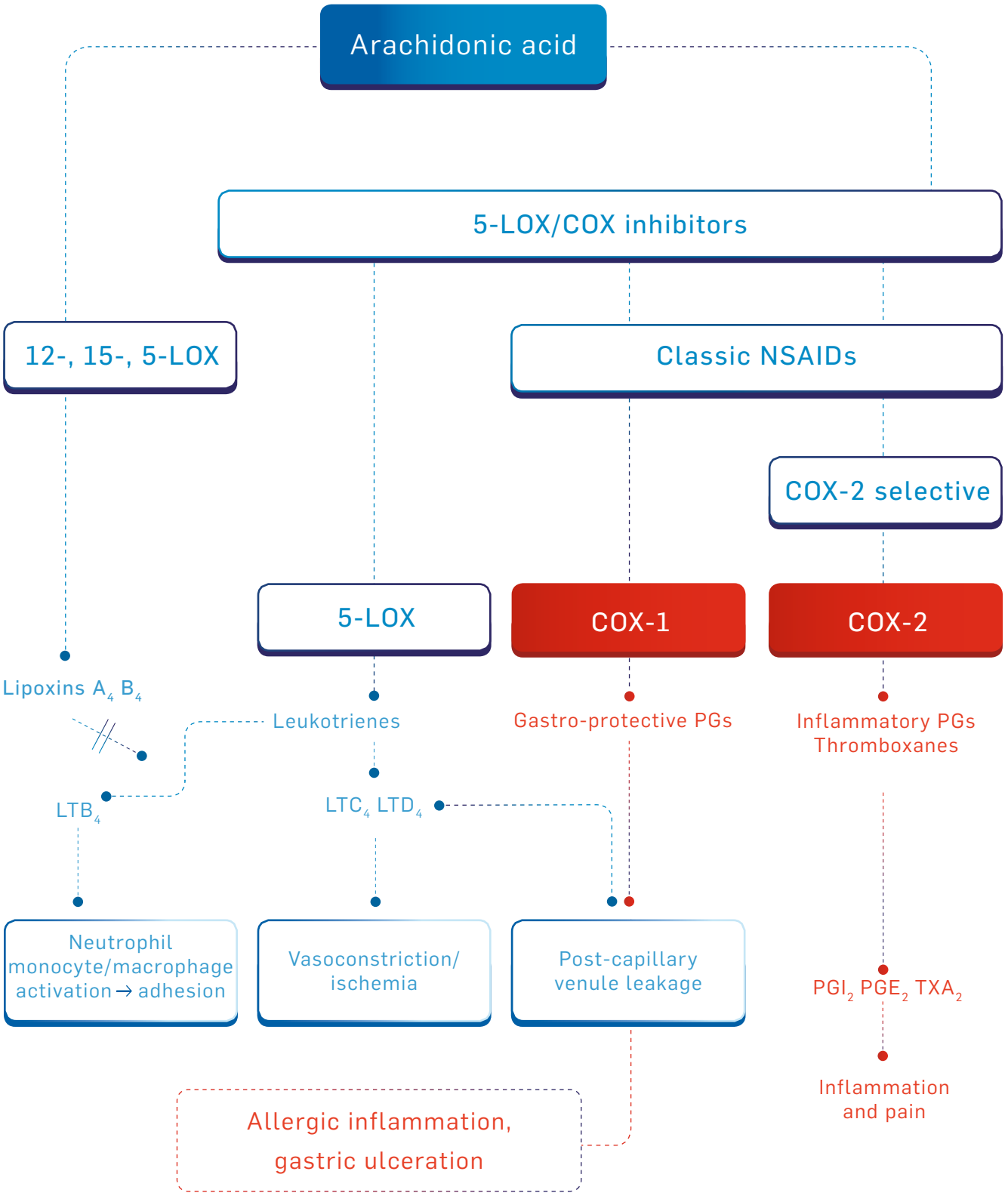
Traumeel®

TRAUMEEL® ACTS ON INFLAMMATORY CYTOKINES RATHER THAN ON COX-1 OR 2 AS IS THE CASE WITH NSAIDS [1-3]

- Traumeel® down-regulates pro-inflammatory cytokines
- Traumeel® up-regulates anti-inflammatory cytokines

TRAUMEEL® - A MULTITARGET, MULTICOMPONENT MEDICATION SUPPORTS INFLAMMATION RESOLUTION AND HELPS TO ACCELERATE THE HEALING PROCESS AND PROVIDES SUSTAINED RECOVERY FROM INJURY [1, 2, 4-11]

...FROM CONVENTIONAL NSAIDS [1,2]



COX, cyclooxygenase; 5-LOX, 5-lipoxygenase; TXA_2, thromboxane A_2; LT, leukotriene; LX, lipoxin; NSAIDs, non-steroidal anti-inflammatory drugs; PG, prostaglandin

Figure 1: Adapted from Martel-Pelletier J et al. Semin Arthritis Rheum. 2003 Dec. [12]

INFLAMMATION RESOLUTION NOT JUST ANTI-INFLAMMATORY ACTION

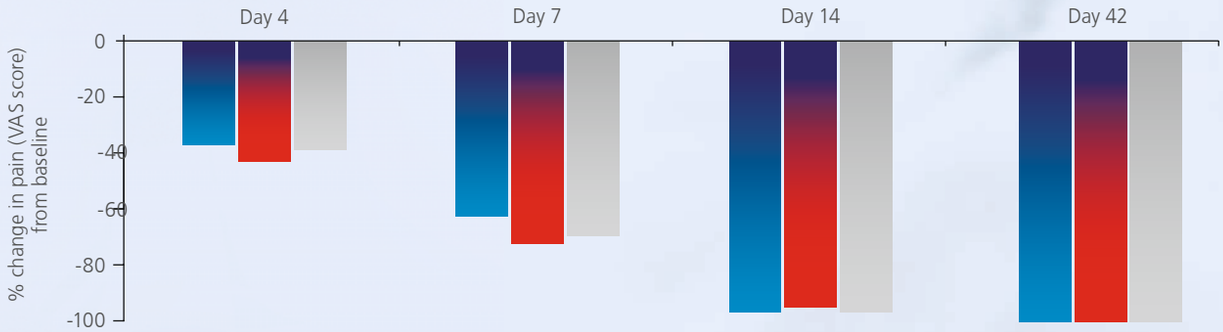
- The unique clinical properties of Traumeel®, its efficacy, effectiveness, and safety demonstrated in numerous clinical trials and observational studies [4-6, 13-16] has been recently supported by our state-of-the-art research in inflammation and inflammation resolution [1, 2]
- Recent studies into the biological action of Traumeel® demonstrate a potential mechanism of action that differs from conventional NSAIDs [1, 2]
- The use of NSAIDs may delay the natural healing process as the inflammation supressed by NSAIDs is a necessary component of tissue recovery [17, 18]

TRAUMEEL® - A BETTER CHOICE FOR PATIENTS WITH MUSCULOSKELETAL INJURIES AND INFLAMMATION

- As effective as diclofenac in reducing pain, swelling and for improving function and mobility in patients with acute ankle sprain [4]
- As effective as NSAIDs for rapid and sustained pain relief in patients with acute injuries [4-6]
- As effective as NSAIDs for improving mobility in patients with acute injuries [4-6]

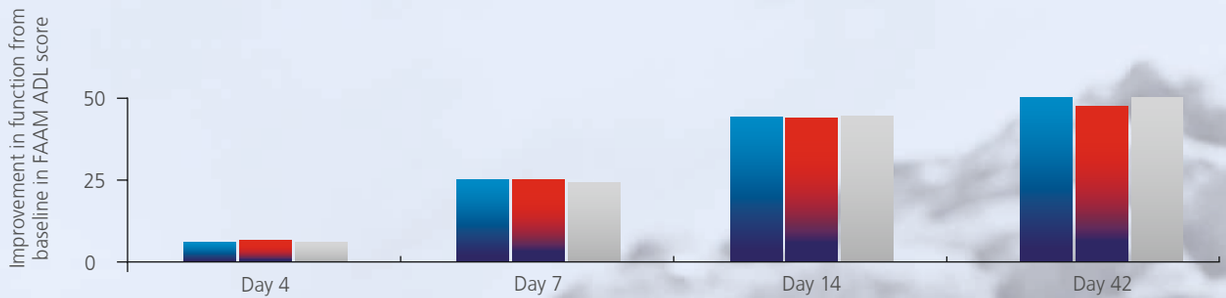
TRAUMEEL® CAN BE USED IN A WIDE RANGE OF MUSCULOSKELETAL INJURIES

Traumeel® reduces pain as effectively as diclofenac at all time points [4]



VAS, Visual Analogue Scale

Traumeel® enables patients to return to normal activities as effectively as diclofenac [4]



FAAM ADL, Foot and Ankle Ability Measure Activities of Daily Living Subscale

Figure 2 and 3: Adapted from González de Vega et al. 2013[4] Traumeel® ointment N=143 Traumeel® gel N=140 Diclofenac 1% gel N=137

TRAUMEEL®: PROVEN EFFICACY COMPARABLE TO NSAIDS, CONVENTIONAL THERAPIES AND SUPERIOR TO PLACEBO [4-6, 13-16, 19, 20]

- Particularly for acute conditions and exacerbations of chronic conditions, symptoms and disorders [4-6, 13-16]
- Injuries include sprains, dislocations, contusions, hemarthrosis and effusions into a joint [21]

TRAUMEEL® - FOR TREATING AND RAPIDLY RESOLVING INFLAMMATION, MUSCLE AND JOINT PAIN

Traumeel® injection improves pain and mobility in acute and/or chronic overuse epicondylitis ('tennis elbow') with significantly better outcomes after week 2 [5]

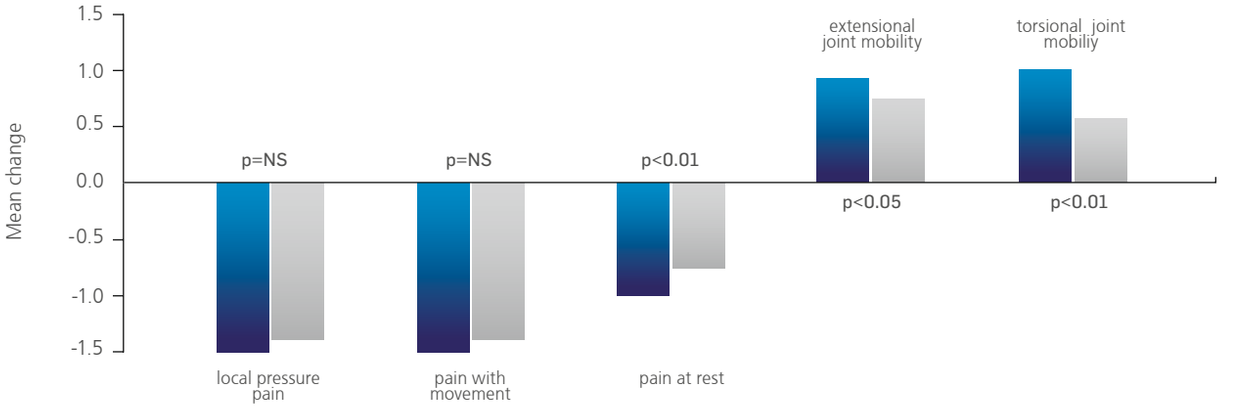
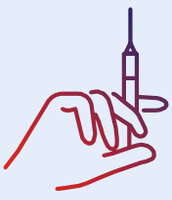
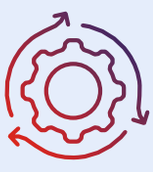


Figure 4: Adapted from Birnesser et al. 2004 [5]

WITH SUPERIOR TOLERABILITY TO DICLOFENAC



- Traumeel® injections provide significantly improved tolerability versus diclofenac [5]



- In patients diagnosed with epicondylitis, after 2 weeks 87.7 % of patients reported ‘very good’ tolerability on Traumeel® versus 44.9 % for diclofenac [5]

“VERY GOOD” TOLERABILITY REPORTED BY PATIENTS DIAGNOSED WITH EPICONDYLITIS ON TRAUMEEL® INJECTION COMPARED WITH NSAIDS [5]

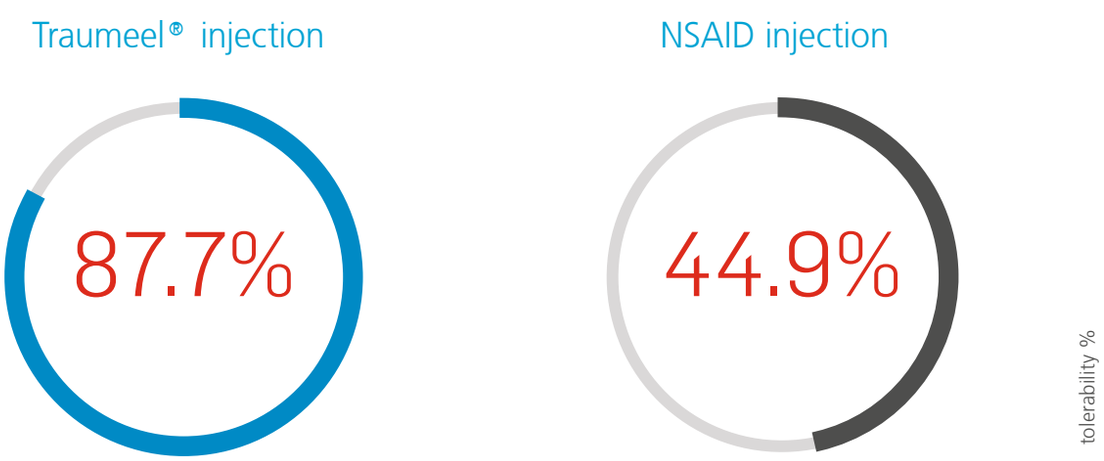
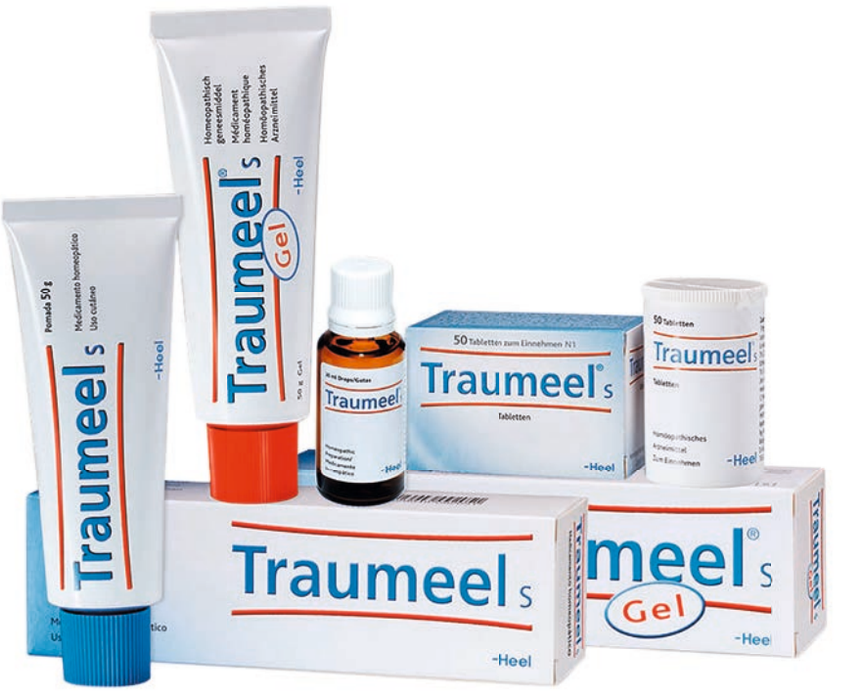


Figure 5: Adapted from Birnesser et al. 2004[5]

TRAUMEEL® HAS A VERY GOOD SAFETY PROFILE [5,6, 13-16]

- It can be used in a wide range of patients, over prolonged periods of time without gastrointestinal bleeding, cardiovascular or renal side effects [14-16, 22]
- Reported adverse effects are very rare with Traumeel® [14-16, 21]
- It has no known interactions with other medications including anticoagulants, [21] unlike diclofenac which has anti-platelet activity [23]
- In vitro study indicates no myotoxic effects [24]
- Traumeel® may reduce exercise-induced muscle damage and exert a protective effect on muscle integrity [9, 10]

TRAUMEEL® IS WELL TOLERATED
[5,6, 13-16]



MULTIPLE FORMULATIONS AND FLEXIBLE FOR ALL PATIENTS

FORMULATIONS	ADMINISTRATION AND DOSAGE			
ACUTE/INITIAL	Adults (and children > 12 years)	Children 6–11 years	Children 2–5 years	Children 0–2 years
 OINTMENT/ GEL	Apply 2× daily, or more often if needed	Apply 2× daily, or more often if needed	Apply 2× daily, or more often if needed	Apply 2× daily, or more often if needed
 TABLETS	1 tablet every ″ to 1 hour, up to 12× daily, and then continue with standard dosage	1 tablet every 1 to 2 hours, up to 8× daily, and then continue with standard dosage	1 tablet every 1 to 2 hours, up to 6× daily, and then continue with standard dosage	1 tablet every 1 to 2 hours, up to 4× daily, and then continue with standard dosage
 INJECTION SOLUTIONS s.c., i.a., i.d., i.m. or i.v. route	1 ampoule daily, and then continue with standard dosage	⅔ of an ampoule daily, and then continue with standard dosage	″ ampoule daily, and then continue with standard dosage	—
 DROPS	10 drops every ″ to 1 hour, up to 12× daily, and then continue with standard dosage	7 drops every ″ to 1 hour, up to 12× daily, and then continue with standard dosage	5 drops every ″ to 1 hour, up to 12× daily, and then continue with standard dosage	3 drops every ″ to 1 hour, up to 12× daily, and then continue with standard dosage
STANDARD	Adults (and children > 12 years)	Children 6–11 years	Children 2–5 years	Children 0–2 years
 OINTMENT/ GEL	Apply 2× daily, or more often if needed	Apply 2× daily, or more often if needed	Apply 2× daily, or more often if needed	Apply 2× daily, or more often if needed
 TABLETS	1 tablet 3× daily	1 tablet 2× daily	1 tablet 1–2× daily	1 tablet 1× daily
 INJECTION SOLUTIONS s.c., i.a., i.d., i.m. or i.v. route	1 ampoule 1 to 3× weekly	⅔ of an ampoule 1 to 3× weekly	″ ampoule 1 to 3× weekly	—
 DROPS	10 drops 3× daily	7 drops 3× daily	5 drops 3× daily	3 drops 3× daily

For further information see package insert.

Please refer to your local CCDS for Traumeel® administration and dosage.

■ Acute/Initial ■ Standard

- Traumeel® is on the approved drugs list of the National Anti Doping Agency (NADA), Germany [25]
- Traumeel® is not listed on the WADA (World Anti-Doping Agency) list of banned products [26]
- Sporting institutions in Italy and Spain acknowledge Traumeel's efficacy and safety in their respective consensus guidelines [27, 28]

TRAUMEEL® - MULTITARGET, MULTICOMPONENT MEDICATION IS COMPOSED OF 14 PLANT EXTRACTS AND MINERALS [21]

ACHILLEA MILLEFOLIUM
(milfoil)

ECHINACEA PURPUREA
(purple cone flower)

ACONITUM NAPELLUS
(monkshood)

HAMAMELIS VIRGINIANA
(witch hazel)

ARNICA MONTANA
(mountain arnica)

HYPERICUM PERFORATUM
(St. John's wort)

ATROPA BELLADONNA
(deadly nightshade)

MATRICARIA RECUTITA
(chamomile)

BELLIS PERENNIS
(daisy)

SYMPHYTUM OFFICINALE
(comfrey)

CALENDULA OFFICINALIS
(calendula)

CALCIUM SULPHIDE
(hepar sulfuris)

ECHINACEA ANGUSTIFOLIA
(narrow-leaved cone flower)

MERCURIO- AMIDONITRATE
(mercurius solubilis hahnemanni)

Traumeel® Summary of Product Characteristics. [21]

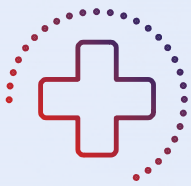
SUMMARY OF PRODUCT CHARACTERISTICS

TRAUMEEL® FORMULATIONS AND DOSING RECOMMENDATIONS

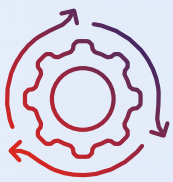
Traumeel®: Tablets • Solution for Injection • Ointment • Gel • Drops

Compositions: Tablets: 1 tablet containing: Active ingredients: Achillea millefolium D3 15.0 mg; Aconitum napellus D3 30.0 mg; Atropa belladonna D4 75.0 mg; Hepar sulfuris D8 30.0 mg; Matricaria recutita D3 24.0 mg; Mercurius solubilis Hahnemanni D8 30.0 mg; Symphytum officinale D8 24.0 mg; Bellis perennis D2 6.0 mg; Calendula officinalis D2 15.0 mg; Echinacea D2 6.0 mg; Echinacea purpurea D2 6.0 mg; Hamamelis virginiana D2 15.0 mg; Hypericum perforatum D2 3.0 mg; Arnica montana D2 15.0 mg. Excipients: Lactose monohydrate 6.0 mg; Magnesium stearate 1.5 mg. Contains lactose! Please see package insert! Solution for Injection: 1 ampoule of 2.2 ml (= 2.2 g) contains: Active ingredients: Achillea millefolium D3 2.20 mg; Matricaria recutita D3 2.20 mg; Symphytum officinale D6 2.20 mg; Aconitum napellus D2 1.32 mg; Atropa belladonna D2 2.20 mg; Bellis perennis D2 1.10 mg; Calendula officinalis D2 2.20 mg; Echinacea D2 0.55 mg; Echinacea purpurea D2 0.55 mg; Hypericum perforatum D2 0.66 mg; Hepar sulfuris D6 2.20 mg; Mercurius solubilis Hahnemanni D6 1.10 mg; Hamamelis virginiana D1 0.22 mg; Arnica montana D2 2.20 mg. Excipients: Sodium chloride 19.4 mg, Water for injections 2179.1 mg. Ointment: 100 g containing: Active ingredients: Achillea millefolium D4 0.090 g; Aconitum napellus D4 0.050 g; Arnica montana D4 1.500 g; Atropa belladonna D4 0.050 g; Bellis perennis D4 0.100 g; Calendula officinalis D4 0.450 g; Echinacea D4 0.150 g; Echinacea purpurea D4 0.150 g; Hamamelis virginiana D4 0.450 g; Hepar sulfuris D6 0.025 g; Hypericum perforatum D6 0.090 g; Matricaria recutita D4 0.150 g; Mercurius solubilis Hahnemanni D6 0.040 g; Symphytum officinale D4 0.100 g. Excipients: Paraffin, liquid 9.342 g; Cetostearyl alcohol (type A), emulsifying 8.007 g; Paraffin, white soft 9.342 g; Water, purified 60.579 g; Ethanol (96%) 9.335 g; Preserved with 12.7 vol.-% alcohol. Gel: 100 g containing: Active ingredients: Achillea millefolium D0 0.090 g; Aconitum napellus D1 0.050 g; Arnica montana D3 1.500 g; Atropa belladonna D1 0.050 g; Bellis perennis D0 0.100 g; Calendula officinalis D0 0.450 g; Echinacea D0 0.150 g; Echinacea purpurea D0 0.150 g; Hamamelis virginiana D0 0.450 g; Hepar sulfuris D6 0.025 g; Hypericum perforatum D6 0.090 g; Matricaria recutita D0 0.150 g; Mercurius solubilis Hahnemanni D6 0.040 g; Symphytum officinale D4 0.100 g. Excipients: Water, purified 74.652 g; Ethanol (96%) 18.653 g; Carbomers (Carbopol 980NF) 1.000 g; Sodium hydroxide solution 18% (m/m) 2.300 g; Contains 24.4 vol.-% alcohol. Purified water, ethanol 96% (V/V), carbomers, sodium hydroxide solution 18% m/m. Drops: 100 g containing: Active ingredients: Aconitum napellus D3 10.0 g; Atropa belladonna D4 25.0 g; Symphytum officinale D8 8.0 g; Achillea millefolium D3 5.0 g; Calendula officinalis D2 5.0 g; Echinacea D2 2.0 g; Echinacea purpurea D2 2.0 g; Hamamelis virginiana D2 5.0 g; Hypericum perforatum D2 1.0 g; Matricaria recutita D3 8.0 g; Hepar sulfuris D8 10.0 g; Mercurius solubilis Hahnemanni D8 10.0 g; Arnica montana D2 5.0 g; Bellis perennis D2 2.0 g. Excipients: Water, purified 2.0 g; Contains 35 vol.-% alcohol. Indications: Tablets, Solution for Injection, Ointment, Gel, Drops: The medicinal product is used for the treatment of various inflammatory conditions including injuries, especially of the musculoskeletal system. Contraindications: Tablets, Solution for Injection, Gel, Drops: Known allergy (hypersensitivity) to one or more of the ingredients, including plants of the daisy family (Asteraceae) such as Arnica montana (arnica), Calendula officinalis (pot marigold), Chamomilla recutita (chamomile), Echinacea (coneflower), Achillea millefolium (yarrow), Bellis perennis (daisy). Ointment: Known allergy (hypersensitivity) to one or more of the ingredients, including plants of the daisy family (Asteraceae) such as Arnica montana (arnica), Calendula officinalis (pot marigold), Chamomilla recutita (chamomile), Echinacea (coneflower), Achillea millefolium (yarrow), Bellis perennis (daisy) and emulsifying cetylstearyl alcohol. Special warnings and special precautions for use: Tablets: Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. As this product contains Echinacea, individual evaluation is recommended before prescribing this product in patients with immune system dysfunction, e.g. cases of progressive systemic disorders, autoimmune diseases, immunodeficiencies, immunosuppression and diseases of the white blood cell system. Solution for Injection: As this product contains Echinacea, individual evaluation is recommended before prescribing this product in patients with immune system dysfunction, e.g. cases of progressive systemic disorders, autoimmune diseases, immunodeficiencies, immunosuppression and diseases of the white blood cell system. Ointment: Cetylstearyl alcohol may cause local skin reactions (e.g. contact dermatitis). Avoid contact with eyes, mucosae, open wounds or broken skin. Gel: Avoid contact with eyes, mucosae, open wounds or broken skin. Drops: This medicinal product contains 35 vol.-% ethanol (alcohol). As this product contains Echinacea, individual evaluation is recommended before prescribing this product in patients with immune system dysfunction, e.g. cases of progressive systemic disorders, autoimmune diseases, immunodeficiencies, immunosuppression and diseases of the white blood cell system.Side effects: Like all medicinal products, this homeopathic medicinal product can cause side effects, although not everybody gets them. Tablets: In isolated cases transient skin reactions have been reported. Solution for Injection: In isolated cases transient allergic (hypersensitivity) reactions (e.g. skin allergies, redness/swelling at the injection site, even up to anaphylaxis) have been reported. Ointment: In isolated cases transient skin reactions have been reported. Gel: In isolated cases transient skin reactions (eg. rash, itchiness) have been reported. Drops: In isolated cases transient allergic skin reactions have been reported. Interactions with other medication: Tablets: None have been reported, and none are expected due to the homeopathic dilutions.Solution for Injection, Drops: No interactions have been reported, and none are expected due to the homeopathic dilutions. Ointment, Gel: No interactions have been reported, and none are expected due to the homeopathic dilutions and external use.Pregnancy and lactation: For this product no clinical data on pregnancy and lactation are available. Homeopathic dilutions of the substances present in this medicinal product are not known to be harmful during pregnancy and lactation. No adverse effects have so far been reported. Effects on ability to drive and use machines: Tablets, Solution for Injection: No effects on the ability to drive and use machines have been reported, and none are expected due to the homeopathic dilutions. Ointment, Gel: Not applicable. Drops: This medicinal product has no or negligible influence on the ability to drive and use machines. Dosage: Tablets: Unless otherwise prescribed: Standard dosage: Adults (and children 12 yrs. and older): 1 tablet 3× daily. Pediatric: below 2 yrs.: 1 tablet 1× daily. 2–5 yrs.: 1 tablet 1–2× daily. 6–11 yrs.: 1 tablet 2× daily. Acute or initial dosage: Adults (and children 12 yrs. and older): 1 tablet every ˝ to 1 hr., up to 12× daily, and then continue with standard dosage. Pediatric: below 2 yrs.: 1 tablet every 1 to 2 hrs., up to 4× daily, and then continue with standard dosage. 2–5 yrs.: 1 tablet every 1 to 2 hrs., up to 6× daily, and then continue with standard dosage. 6–11 yrs.: 1 tablet every 1 to 2 hrs., up to 8× daily, and then continue with standard dosage. Method of administration: Preferably allow the tablet to dissolve in the mouth, and then swallow. For children it is possible to crush the tablet and add to a small amount of water. This medicine should be taken away from meals. Solution for Injection: unless otherwise prescribed: Standard dosage: Adults (and children 12 yrs. and older): 1 ampoule 1 to 3× weekly. Pediatric: 2–5 yrs.: ˝ ampoule 1 to 3x weekly. 6–11 yrs.: ⅔ of an ampoule 1 to 3× weekly. Acute or initial dosage: Adults (and children 12 yrs. and older): 1 ampoule daily, and then continue with standard dosage. Pediatric: 2–5 yrs.: ˝ ampoule daily, and then continue with standard dosage. 6–11 yrs.: ⅔ of an ampoule daily, and then continue with standard dosage. Method of administration: Solution for Injection: may be administered by the s.c., i.a., i.d., i.m. or i.v. route. Ointment, Gel: Unless otherwise prescribed: Standard dosage: Adults (and children 12 yrs. and older): apply 2× daily, or more often if needed. Paediatric: below 2 yrs.: apply 2× daily, or more often if needed. 2–5 yrs.: apply 2× daily, or more often if needed. 6–11 yrs.: apply 2× daily, or more often if needed. Method of administration: for external use only. Apply generously to the affected area. Traumeel® may be applied using mild compression bandaging and/or occlusive bandaging. Drops: unless otherwise prescribed: Standard dosage: Adults (and children 12 yrs. and older): 10 drops 3× daily. Pediatric: below 2 yrs.: 3 drops 3× daily. 2–5 yrs.: 5 drops 3× daily. 6–11 yrs.: 7 drops 3× daily. Acute or initial dosage: Adults (and children 12 yrs. and older): 10 drops every ˝ to 1 hr., up to 12× daily, and then continue with standard dosage. Pediatric: below 2 yrs.: 3 drops every ˝ to 1 hr., up to 12× daily, and then continue with standard dosage. 2–5 yrs.: 5 drops every ˝ to 1 hr., up to 12× daily, and then continue with standard dosage. 6–11 yrs.: 7 drops every ˝ to 1 hr., up to 12× daily, and then continue with standard dosage. Method of administration: This medicine should be taken away from meals. For children, add drops to a small amount of water. Duration of use: Tablets, Solution for Injection, Drops: As this product contains Echinacea, individual evaluation is recommended before prescribing this product for periods longer than 8 weeks. Overdose: Tablets, Solution for Injection, Drops: No cases of overdose have been reported, and none are expected due to the homeopathic dilutions. Ointment, Gel: No cases of overdose have been reported, and none are expected due to the homeopathic dilutions and external use. Package sizes: Tablets: Packs containing 50 and 250 tablets. (9753) Solution for Injection: Packs containing 5, 10, 50 and 100 ampoules of 2.2 ml. (8561) Ointment: Tubes containing 50 and 100 g of ointment. (9932). Gel: Tubes containing 50 and 100 g of gel. (9934) Drops: Drop bottles containing 30 and 100 ml. (9804). Version 2016

A PATH TO SUSTAINABLE RECOVERY WITH TRAUMEEL®



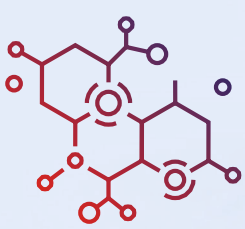
- A multitarget, multicomponent medication supports inflammation resolution, helps to accelerate the healing process and provides sustained recovery from injury [1,2] [4-6, 9-11]



- Efficacy, speed of onset and improved mobility at least as good as NSAIDs in sports injuries [4-6]

- Better tolerated than diclofenac [5,6] (especially in GI and cardiovascular side effects) [14-16, 22]

- Different mechanism of action to NSAIDs [1, 2]



- A wide range of different formulations to best suit your patient [14-16, 21]

- 14 ingredients working together [11, 29] to deliver effective and well tolerated relief of inflammation symptoms

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