

MULTITARGETED AND COMPREHENSIVE

# The Bioregulatory Approach to Fibromyalgia Syndrome



**-Heel**

Healthcare designed by nature

# A Typical Patient

## Nancy, 42-year-old audiologist

The patient presents with widespread pain. Other reported symptoms include severe brain fog, increasing episodes of anxiety attacks, sleep disturbances, and fatigue.

Onset of current symptoms occurred two years ago following a motor vehicle accident. Pertinent family history includes early parental separation. Current signs include orthostatic hypotension and multiple tender trigger points upon palpation including 18 points specific for the American College of Rheumatology (ACR) diagnosis of fibromyalgia. Polysomnography shows restless legs syndrome with sleep-disordered breathing.

Previous medical treatments include slow-release nonsteroidal anti-inflammatory drugs (NSAIDs) when necessary and gabapentin for pain. Other current prescriptions include a selective serotonin reuptake inhibitor (SSRI).

Because of limited improvement in symptoms as well as severe side effects from the gabapentin (including blurred vision, shaking, and general swelling), she requests further consultation from a doctor who uses a bioregulatory approach.

## Diagnosis

Fibromyalgia  
syndrome



# Medical Needs

Current treatment options<sup>1,2</sup>

- › **Pharmacological**
  - Tricyclic antidepressants (e.g., amitriptyline)
  - Pregabalin, gabapentin
  - NMDA receptor antagonists (e.g., dextromorphan)
- › **Nonpharmacological**
  - Sleep hygiene
  - Protrusion splints and continuous positive airway pressure (CPAP) for sleep-disordered breathing
  - Graded exercise program
  - Cognitive behavioral therapy (CBT)

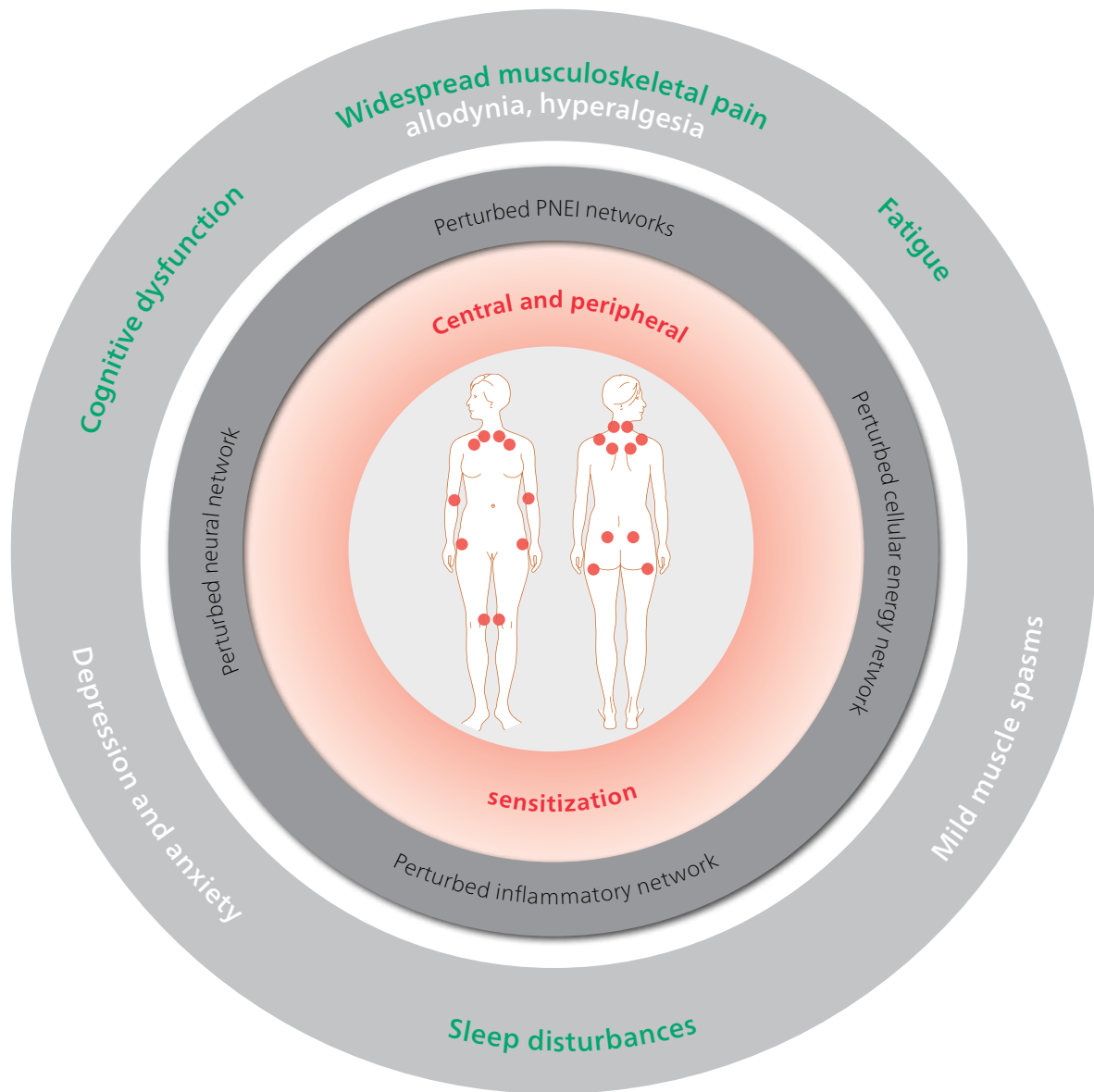
Optimization potential of current treatments

- › A follow-up study in patients with fibromyalgia syndrome showed
  - Symptoms of pain improved only moderately in 25% of the patients
  - No “clinically meaningful” improvements in overall symptom severity<sup>3</sup>
- › Many patients experience side effects that necessitate discontinuation of treatment
- › Focus on treating symptoms without targeting the underlying perturbed networks
- › If multiple concomitant medications are required, products are often not compatible

Needs for a better treatment

- › Multitarget approach to the key underlying perturbed networks in fibromyalgia syndrome
  - Addressing the dysregulated inflammatory network
  - Correcting the dysfunction in the psychoneuroendocrinology (PNEI) networks
  - Treating the affected neural network
  - Supporting the impaired cellular energy network
  - Restoring the mucosal barrier function and the microbiome
- › Multiple concomitant medications should
  - be comprehensive
  - be well tolerated
  - treat underlying perturbed networks and not only signs and symptoms

# Causes | Symptoms | Perturbed Networks

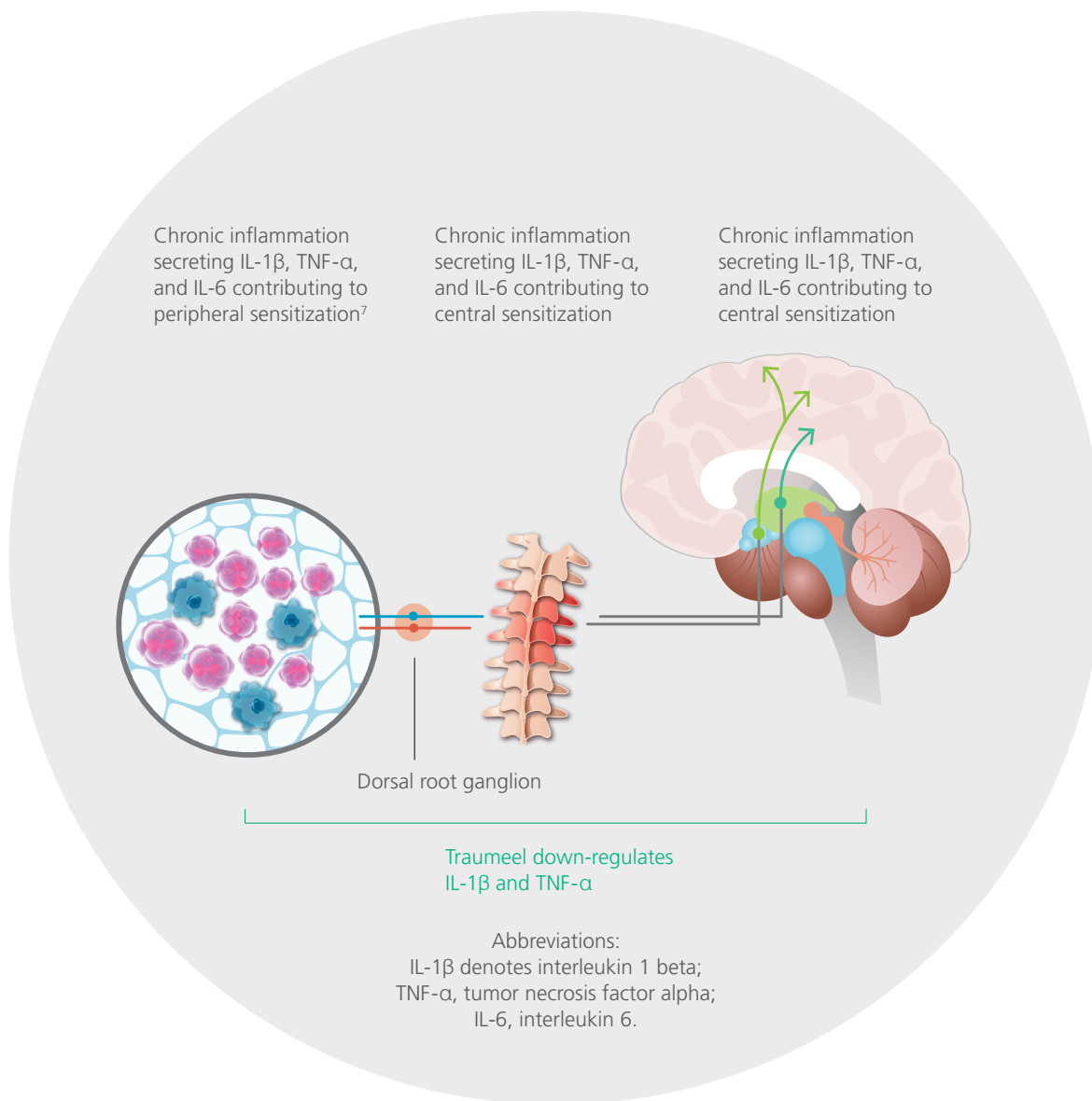


\* Exposome: "The cumulative measure of environmental influences and associated biological responses throughout the lifespan, including exposures from the environment, diet, behavior, and endogenous processes."<sup>4</sup>

## Fibromyalgia Syndrome

- › Is a medical disorder characterized by central and peripheral pain sensitization, resulting in widespread chronic musculoskeletal pain, allodynia, and hyperalgesia
- › Other symptoms include prolonged mild muscle spasms, chronic sleep disturbances, fatigue, and cognitive dysfunction ("fibrofog")
- › Associated symptoms include chronic headaches, anxiety, and depression
- › Has a high association with other functional somatic syndromes (i.e., central sensitivity syndromes)
- › Is associated with a significant negative impact on quality of life
- › The initiating and contributing factors of fibromyalgia syndrome are not completely understood but include genetics and epigenetics, persistent and/or psychological stress including childhood trauma, poor lifestyle choices, nutritional deficiencies, mitochondrial dysfunction, altered microbiome, and negative health effects of the exposome\*<sup>1</sup>
- › Incurs high costs to the health care system<sup>5,6</sup> due to a delay in diagnosis and to multidimensional and prolonged treatment courses

# Traumeel® – the Cornerstone



## Traumeel®

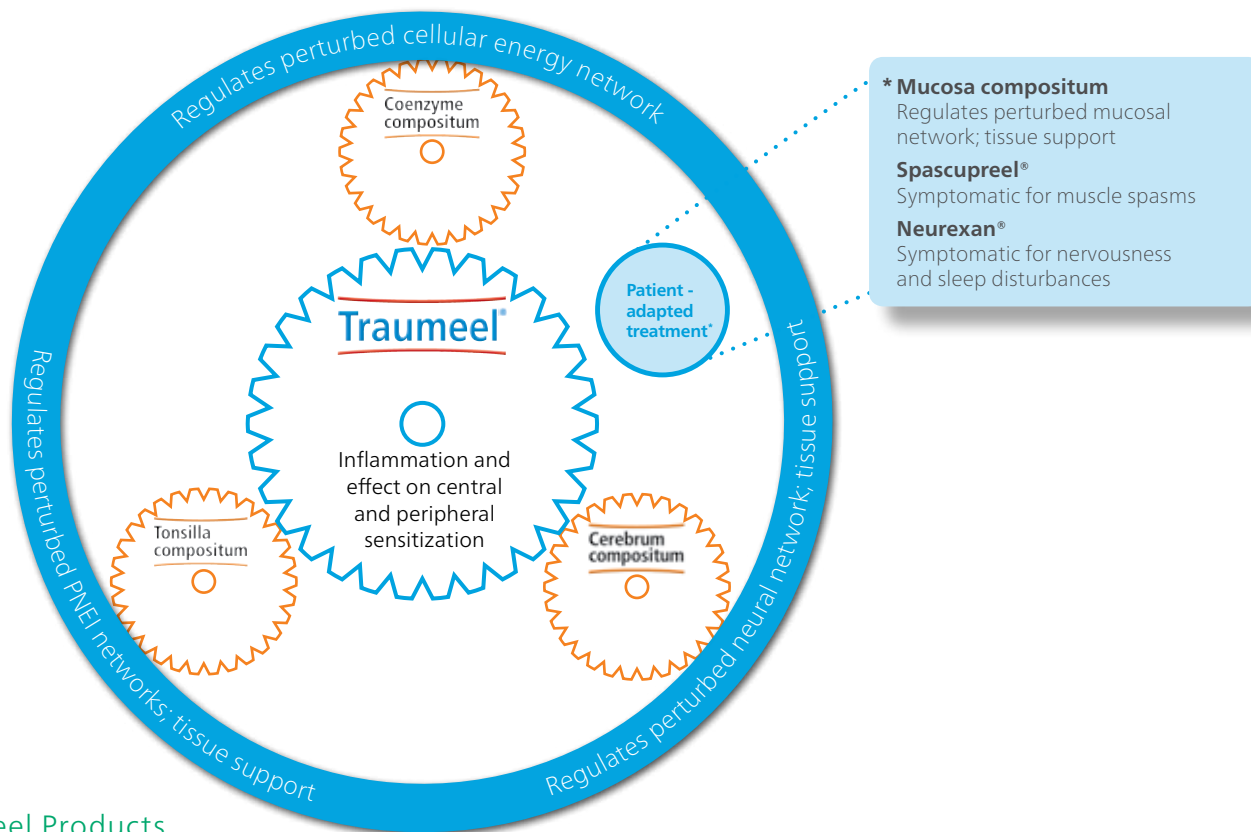
- › May prevent and treat central and peripheral sensitization through its effects on proinflammatory and anti-inflammatory cytokines
  - Thus reducing abnormal pain perception
  - Thus reducing pain
- › No known drug interactions
- › Well tolerated
- › Multiple galenic forms to suit the needs of all patients



# The Cogwheel Principle

## The new multitarget comprehensive treatment approach:

Combining cornerstone Traumeel® with additional Heel products according to key underlying perturbed networks causing predominant signs and symptoms



## Cogwheel Products

	Regulates per- turbed inflam- matory network; effect on central and peripheral sensitization	Regulates perturbed cellular energy network	Regulates per- turbed neural network; tissue support	Regulates perturbed PNEI networks; tissue support	Regulates perturbed mucosal network; tissue support	Symptomatic for muscle spasms	Symptom- atic for nervousness and sleep disturbances
<b>Traumeel®</b>	■						
<b>Coenzyme compositum</b>		■					
<b>Cerebrum compositum</b>			■				
<b>Tonsilla compositum</b>				■			
<b>Mucosa compositum</b>					■		
<b>Spascupreel®</b>						■	
<b>Neurexan®</b>							■

## Good Effectiveness

- › Cornerstone Traumeel® addresses the perturbed inflammatory network by modulating cytokines and therefore, provides effective and long-term pain relief
- › Additional Heel products work comprehensively on individual symptoms arising from specific perturbed networks
- › Excellent tolerability and safety profile
- › No known interactions with other medications

## THE BIOREGULATORY APPROACH

# Examples of Patients\*

### Nancy, 42-year-old audiologist

**Fibromyalgia after stress and motor vehicle accident**



The patient presents with widespread pain. Other reported symptoms include severe brain fog, increasing episodes of anxiety attacks, sleep disturbances, and fatigue. Onset of current symptoms occurred two years ago following a motor vehicle accident. Pertinent family history includes early parental separation.

Current signs include orthostatic hypotension and multiple tender trigger points upon palpation including 18 points specific for the ACR diagnosis of fibromyalgia. Polysomnography shows restless legs syndrome with sleep-disordered breathing. Previous medical treatments include slow-release NSAIDs when necessary and gabapentin for pain. Other current prescriptions include an SSRI. Because of limited improvement in symptoms as well as severe side effects from the gabapentin (including blurred vision, shaking, and general swelling), she requests further consultation from a doctor who uses medications with bioregulatory properties as well as nonpharmacological treatment such as CBT, protraction splinting for sleep-disordered breathing, etc., as part of her treatment plan.

### Eugenia, 52-year-old nurse

**Fibromyalgia after tick bite fever**



The patient was well and very active until four years prior, when she contracted a tick bite fever on a hike in central Africa. She was given antibiotics and rapidly recovered, but then had a relapse and was prescribed another two courses of doxycycline.

Despite most of the acute symptoms resolving and all the blood titers returning to normal, she developed chronic musculoskeletal pain, nonrefreshing sleep with initiation insomnia as well as severe cognitive dysfunction. She also developed intermittent abdominal bloating and diarrhea.

A full work-up of blood, stool, and urine sample as well as imaging studies were then completed with no detectable abnormalities other than increased permeability of the gut. Upon physical examination, the patient fulfilled the revised ACR criteria for FMS. She was informed of her treatment choices, including either hypnotics, pregabalin, as well as antidepressants or to try a pure bioregulatory approach first. The patient, after consulting with her general practitioner, chose the latter option. Treatment commenced immediately using medications with bioregulatory properties as well as nonpharmacological interventions, especially CBT and dietary advice (i.e., low in refined sugar, gluten, and dairy products).

### Marvin, 34-year-old owner of a dry cleaning company

**Posttraumatic stress disorder with fibromyalgia**



The patient presented a few months after he was severely assaulted and robbed in his dry cleaning establishment. Despite getting professional counseling for a posttraumatic stress disorder (PTSD), he still experienced increased widespread pain, headaches, and cognitive dysfunction.

Further complications included severely disturbed sleep with frequent nightmares as well as depression and anxiety. He had several work-ups to rule out life-threatening disease, but no abnormalities were found except an increased cortisol response on a tetracosactide challenge test, compatible with his PTSD. Metabolomics testing demonstrated abnormalities in his liver detoxification abilities as well as dysfunction of the cellular energy network that could be due to constant exposure to hydrocarbon solvents used in dry cleaning. He was taking several medications for his PTSD, including an SSRI for depression as well as a benzodiazepine for panic attacks and sleep disturbances. Fibromyalgia syndrome was diagnosed recently by a rheumatologist, and pregabalin was prescribed but discontinued following a severe reaction (i.e., euphoria). A colleague informed him about a successful adjuvant approach for FMS using medications with bioregulatory properties and lifestyle adjustment and therefore, he was seeking further treatment.

Signs and symptoms

Recommendation

Expected outcome

**Traumeel®**  
**Tonsilla compositum**  
**Coenzyme compositum**  
**Cerebrum compositum**  
**Neurexan®** symptomatic for nervousness and sleep disturbances  
**Spascupreel®** symptomatic for muscle spasms

**Traumeel®**  
**Tonsilla compositum**  
**Cerebrum compositum**  
**Coenzyme compositum**  
**Neurexan®** initially for sleep disturbances  
**Mucosa compositum** one cycle for perturbed mucosal network

**Traumeel®**  
**Coenzyme compositum**  
**Cerebrum compositum**  
**Hepar compositum** for the liver overload from toxicants

There was general improvement of overall symptoms within two weeks of commencing the treatments using medications with bioregulatory properties.

The first noticeable changes were improvement in the sleep pattern, reduced anxiety during the day, and improved cognitive function. The dose of gabapentin was reduced first by tapering over one month. The use of SSRIs also was reduced, but more slowly due to some relapses of mental health symptoms.

Over time, all symptoms improved with two notable relapses following markedly stressful events. After three treatment cycles, the patient was free of pharmaceutical drugs, and the quality of life score (i.e., SF 36) showed much improvement. Neurexan was still taken as needed.

The first noticeable improvement was in her sleep and mood as well as abdominal symptoms. Over a period of nine weeks, the other cardinal symptoms, namely widespread musculoskeletal pain, fatigue, and "fibro-fog" also improved. She also noticed an increase in her activities and social life due to the reduction in pain and improved cognitive function.

However, when the treatment was reduced, her pain and fibro-fog came back and therefore, it was recommended she continued using Cerebrum compositum and Traumeel® for another eight weeks.

After this period, she only used Traumeel® p.r.n. for pain and Neurexan for sleep disturbances when necessary.

The patient remained on his SSRI and benzodiazepine, but the aim was to wean him fairly quickly from the latter once the Cerebrum compositum started to have an effect.

The patient quickly noticed a reduction in pain and muscle stiffness as well as improvement in his cognitive dysfunction. His mood improved as well and he had more energy to fulfill his daily tasks. Gradually, over twelve weeks, all his FMS symptoms improved with the treatment regimen. He was weaned off the benzodiazepine after four weeks, replacing this with Neurexan.

He had one relapse due to a stressful period, was put on another cycle of treatment and in general is doing well, still taking the SSRI and going for CBT.

\* Please note that these are not real patient cases; however, they reflect highly probable clinical scenarios.

## References

1. Henningsen P, Zipfel S, Herzog W. Management of functional somatic syndromes. *Lancet*. 2007;369(9565):946-955.
2. Dadabhoj D, Clauw DJ. Therapy Insight: fibromyalgia—a different type of pain needing a different type of treatment. *Nat Clin Pract Rheumatol*. 2006;2(7):364-372.
3. Walitt B, Fitzcharles MA, Hassett AL, Katz RS, Häuser W, Wolfe F. The longitudinal outcome of fibromyalgia: a study of 1555 patients. *J Rheumatol*. 2011;38(10):2238-2246.
4. Miller GW, Jones DP. The nature of nurture: refining the definition of the exposome. *Toxicol Sci*. 2014;137(1):1-2.
5. Martinez JE. Fibromyalgia and the old dilemma: theory vs. practice. *Psychol Neurosci*. 2014;7(1):9-14.
6. Hawkins RA. Fibromyalgia: a clinical update. *J Am Osteopath Assoc*. 2013;113(9):680-689.
7. Kawasaki Y, Zhang L, Cheng JK, Ji RR. Cytokine mechanisms of central sensitization: distinct and overlapping role of interleukin-1beta, interleukin-6, and tumor necrosis factor-alpha in regulating synaptic and neuronal activity in the superficial spinal cord. *J Neurosci*. 2008;28(20):5189-5194.

## Product information

### Cerebrum comp N Summary of Product Characteristics

#### Tablets - Injection solution

**Compositions:** **Tablets:** 1 tablet (301.5 mg) contains: Active ingredients: Acidum phosphoricum D10 1 mg, Aconitum napellus D6 1 mg, Aesculus hippocastanum D4 1 mg, Anamirta cocculus D4 1 mg, Arnica montana D28 1 mg, Cerebrum suis D8 1 mg, Cinchona pubescens D4 1 mg, Conium maculatum D12 1 mg, Embryo totalis suis D10 1 mg, Gelsemium sempervirens D6 1 mg, Hepar suis D10 1 mg, Hyoscyamus niger D6 1 mg, Kalium bichromicum D8 1 mg, Kalium phosphoricum D6 1 mg, Magnesium phosphoricum D10 1 mg, Placenta totalis suis D10 1 mg, Ruta graveolens D4 1 mg, Selenium D10 1 mg, Semecarpus anacardium D6 1 mg, Strychnos ignatii D8 1 mg, Sulfur D10 1 mg, Thuja occidentalis D6 1 mg. Excipients: Lactose monohydrate 298.0 mg, Magnesium stearate 1.5 mg. **Injection solution:** 1 ampoule (2.2 g) contains: Active ingredients: Acidum phosphoricum D10 22.0 mg, Aconitum napellus D6 22.0 mg, Aesculus hippocastanum D4 22.0 mg, Ambra grisea D10 22.0 mg, Anamirta cocculus D4 22.0 mg, Arnica montana D28 22.0 mg, Cerebrum suis D8 22.0 mg, Cinchona pubescens D4 22.0 mg, Conium maculatum D4 22.0 mg, Embryo totalis suis D10 22.0 mg, Gelsemium sempervirens D4 22.0 mg, Hepar suis D10 22.0 mg, Hyoscyamus niger D6 22.0 mg, Kalium bichromicum D8 22.0 mg, Kalium phosphoricum D6 22.0 mg, Magnesium phosphoricum D10 22.0 mg, Manganum phosphoricum D8 22.0 mg, Placenta totalis suis D10 22.0 mg, Ruta graveolens D4 22.0 mg, Selenium D10 22.0 mg, Semecarpus anacardium D6 22.0 mg, Strychnos ignatii D8 22.0 mg, Sulfur D10 22.0 mg, Thuja occidentalis D6 22.0 mg. Excipients: Sodium chloride 19.2 mg, water for injections 1672.0 mg. **Indications:** **Tablets, injection solution:** Support in functional and degenerative disorders of the CNS (Central Nervous System). **Contraindications:** **Tablets, injection solution:** Known allergy (hypersensitivity) to one or more of the ingredients. **Special warnings and special precautions for use:** **Tablets, injection solution:** Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. **Injection solution:** None. **Side effects:** **Tablets:** None have been reported. **Injection solution:** Allergic (hypersensitivity) reactions (e.g. respiratory distress) may occur in very rare cases (i.e. affects less than 1 in 10,000 users). **Interactions with other medication:** **Tablets, injection solution:** No interactions have been reported, and none are expected due to the homeopathic dilutions. **Pregnancy and lactation:** **Tablets, injection solution:** For this product no clinical data on pregnancy and lactation are available. Homeopathic dilutions of the substances present in this medicament are not known to be toxic during pregnancy and lactation. No adverse effects have so far been reported. Effects on ability to drive and use machines: **Tablets, injection solution:** No effects on the ability to drive and use machines have been reported, and none are expected due to the homeopathic dilutions. **Dosage:** **Tablets: Standard dosage:** Adults (and children 12 yrs. and older): 1 tablet 3x daily. **Pediatric:** Below 2 yrs.: 1 tablet 1x daily. 2–5 yrs.: 1 tablet 1–2x daily. 6–11 yrs.: 1 tablet 2x daily. **Acute or initial dosage:** Adults (and children 12 yrs. and older): 1 tablet every 1/2 to 1 hr., up to 12x daily, and then continue with standard dosage. **Pediatric:** Below 2 yrs.: 1 tablet every 1 to 2 hrs., up to 4x daily, and then continue with standard dosage. 2–5 yrs.: 1 tablet every 1 to 2 hrs., up to 6x daily, and then continue with standard dosage. 6–11 yrs.: 1 tablet every 1 to 2 hrs., up to 8x 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. **Injection solution: Standard dosage:** Adults (and children 12 yrs. and older): 1 ampoule 1 to 3x weekly. **Pediatric:** 2–5 yrs.: 1/2 ampoule 1 to 3x weekly. 6–11 yrs.: 2/3 of an ampoule 1 to 3x 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.: 1/2 ampoule daily, and then continue with standard dosage. 6–11 yrs.: 2/3 of an ampoule daily, and then continue with standard dosage. **Method of administration:** Cerebrum comp., Solution for injection may be administered by the s.c., i.d., i.m. or i.v. route. **Overdose:** **Tablets, injection solution:** No cases of overdose have been reported, and none are expected due to the homeopathic dilutions. **Package sizes:** **Tablets (44180):** Packs containing 50 and 250 tablets. **Injection solution(9475):** Packs containing 5, 10, 50 and 100 ampoules of 2.2 ml each.

### Coenzyme comp. Summary of Product Characteristics:

#### Tablets - Injection solution

**Compositions:** **Tablets:** 1 tablet = 301.5 mg containing: Active ingredients: Acidum cis-aconiticum D8 1.0 mg, Acidum ascorbicum D6 1.0 mg, Acidum citricum D8 1.0 mg, Acidum fumaricum D8 1.0 mg, Acidum alpha-ketoglutaricum D8 1.0 mg, Acidum malicum D8 1.0 mg, Acidum succinicum D8 1.0 mg, Adenosinum triphosphoricum D10 1.0 mg, Beta vulgaris rubra D1.0 mg, Coenzym A D8 1.0 mg, Cysteinum D6 1.0 mg, Nadiidum D8 1.0 mg, Natrium pyruvicum D8 1.0 mg, Natrium riboflavinum phosphoricum D6 1.0 mg, Nicotinamidum D6 1.0 mg, Pulsatilla pratensis D6 1.0 mg, Pyridoxinum hydrochloricum D6 1.0 mg, Sulfur D10 1.0 mg, Thiaminum hydrochloricum D6 1.0 mg, Acidum thiocticum D6 1.0 mg, Barium oxalsuccinicum D10 1.0 mg, Cerium oxalicum D8 1.0 mg, Hepar sulfuris D10 1.0 mg, Magnesium oroticum dihydricum D6 1.0 mg, Manganum phosphoricum D6 1.0 mg, Natrium diethylxalacetatum D6 1.0 mg. Excipients: Lactose monohydrate 293.0 mg, Magnesium stearate 1.5 mg. **Injection solution:** 2.2 g containing: Acidum ascorbicum D6 22.0 mg, Acidum alpha-ketoglutaricum D8 22.0 mg, Acidum cis-aconiticum D8 22.0 mg, Acidum citricum D8 22.0 mg, Acidum fumaricum D8 22.0 mg, Acidum malicum D8 22.0 mg, Acidum succinicum D8 22.0 mg, Adenosinum triphosphoricum D10 22.0 mg, Barium oxalsuccinicum D10 22.0 mg, Beta vulgaris

rubra D4 22.0 mg, Coenzym A D8 22.0 mg, Cysteinum D6 22.0 mg, Hepar sulfuris D10 22.0 mg, Nadiidum D8 22.0 mg, Natrium pyruvicum D8 22.0 mg, Natrium riboflavinum phosphoricum D6 22.0 mg, Nicotinamidum D6 22.0 mg, Pulsatilla pratensis D6 22.0 mg, Pyridoxinum hydrochloricum D6 22.0 mg, Sulfur D10 22.0 mg, Thiaminum hydrochloricum D6 22.0 mg, Acidum thiocticum D6 22.0 mg, Cerium oxalicum D8 22.0 mg, Magnesium oroticum dihydricum D6 22.0 mg, Manganum phosphoricum D6 22.0 mg, Natrium diethylxalacetatum D6 22.0 mg. Excipients: Sodium chloride 19.4 mg, water for injections 1628.0 mg. **Indications:** **Tablets, injection solution:** Stimulation of blocked intracellular respiratory enzymatic systems in degenerative diseases. **Contraindications:** **Tablets, injection solution:** Known allergy (hypersensitivity) to one or more of the ingredients. **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. **Injection solution:** None. **Side effects:** **Tablets:** None have been reported. **Injection solution:** Allergic (hypersensitivity) reactions (e.g. skin allergies, redness/swelling at the injection site) may occur in very rare cases (i.e. affects less than 1 in 10,000 users). **Interactions with other medication:** **Tablets, injection solution:** No interactions have been reported, and none are expected due to the homeopathic dilutions. **Pregnancy and lactation:** **Tablets, injection solution:** For this product no clinical data on pregnancy and lactation are available. Homeopathic dilutions of the substances present in this medicament are not known to be toxic during pregnancy and lactation. No adverse effects have so far been reported. Effects on ability to drive and use machines: **Tablets, injection solution:** No effects on the ability to drive and use machines have been reported, and none are expected due to the homeopathic dilutions. **Dosage:** **Tablets: Standard dosage:** Adults (and children 12 yrs. and older): 1 tablet 3x daily. **Pediatric:** Below 2 yrs.: 1 tablet 1x daily. 2–5 yrs.: 1 tablet 1–2x daily. 6–11 yrs.: 1 tablet 2x daily. **Acute or Initial Dosage:** Adults (and children 12 yrs. and older): 1 tablet every 1/2 to 1 hr., up to 12x daily, and then continue with standard dosage. **Pediatric:** Below 2 yrs.: 1 tablet every 1 to 2 hrs., up to 4x daily, and then continue with standard dosage. 2–5 yrs.: 1 tablet every 1 to 2 hrs., up to 6x daily, and then continue with standard dosage. 6–11 yrs.: 1 tablet every 1 to 2 hrs., up to 8x 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. **Injection solution: Standard dosage:** Adults (and children 12 yrs. and older): 1 ampoule 1 to 3x weekly. **Pediatric:** 2–5 yrs.: 1/2 ampoule 1 to 3x weekly. 6–11 yrs.: 2/3 of an ampoule 1 to 3x 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.: 1/2 ampoule daily, and then continue with standard dosage. 6–11 yrs.: 2/3 of an ampoule daily, and then continue with standard dosage. **Method of Administration:** Coenzyme comp., Solution for injection may be administered by the s.c., i.d., i.m. or i.v. route. **Overdose:** **Tablets, injection solution:** No cases of overdose have been reported, and none are expected due to the homeopathic dilutions. **Package sizes:** **Tablets:** Packs containing 50 and 250 tablets. **Injection solution:** Packs containing 5, 10, 50 and 100 ampoules of 2.2 ml each.

### Mucosa comp.-Heel Summary of Product Characteristics:

#### Tablets - Injection solution

**Compositions:** **Tablets:** 1 tablet = 301.5 mg containing: Active ingredients: Argentum nitricum D6 1.0 mg, Atropa bella-donna D10 1.0 mg, Ceanothus americanus D4 1.0 mg, Hydrastis canadensis D6 1.0 mg, Kalium bichromicum D8 1.0 mg, Kreosotum D12 1.0 mg, Lachesis D10 1.0 mg, Mandragora e radice siccata D10 1.0 mg, Marsdenia cundurango D6 1.0 mg, Momordica balsamina D6 1.0 mg, Mucosa coli suis D8 1.0 mg, Mucosa ductus choledochi suis D8 1.0 mg, Mucosa duodeni suis D8 1.0 mg, Mucosa ilei suis D8 1.0 mg, Mucosa jejuni suis D8 1.0 mg, Mucosa nasalis suis D8 1.0 mg, Mucosa oculi suis D8 1.0 mg, Mucosa oesophagi suis D8 1.0 mg, Mucosa oris suis D8 1.0 mg, Mucosa pulmonis suis D8 1.0 mg, Mucosa pylori suis D8 1.0 mg, Mucosa recti suis D8 1.0 mg, Mucosa vesicae felleae suis D8 1.0 mg, Mucosa vesicae urinae suis D8 1.0 mg, Oxalis acetosella D6 1.0 mg, Pankreas suis D10 1.0 mg, Phosphorus D8 1.0 mg, Psychotria ipecacuanha D8 1.0 mg, Pulsatilla pratensis D6 1.0 mg, Semecarpus anacardium D6 1.0 mg, Strychnos nux-vomica D13 1.0 mg, Sulfur D8 1.0 mg, Ventriculus suis D8 1.0 mg, Veratrum album D6 1.0 mg. Excipients: Lactose monohydrate 300 mg, Magnesium stearate 1.5 mg. **Injection solution:** 2.2 g containing: Active ingredients: Argentum nitricum D6 22.0 mg, Atropa bella-donna D10 22.0 mg, Ceanothus americanus D4 22.0 mg, Hydrastis canadensis D4 22.0 mg, Kalium bichromicum D8 22.0 mg, Kreosotum D10 22.0 mg, Lachesis D10 22.0 mg, Mandragora e radice siccata D10 22.0 mg, Marsdenia cundurango D6 22.0 mg, Momordica balsamina D6 22.0 mg, Mucosa coli suis D8 22.0 mg, Mucosa ductus choledochi suis D8 22.0 mg, Mucosa duodeni suis D8 22.0 mg, Mucosa ilei suis D8 22.0 mg, Mucosa jejuni suis D8 22.0 mg, Mucosa nasalis suis D8 22.0 mg, Mucosa oculi suis D8 22.0 mg, Mucosa oesophagi suis D8 22.0 mg, Mucosa oris suis D8 22.0 mg, Mucosa pulmonis suis D8 22.0 mg, Mucosa pylori suis D8 22.0 mg, Mucosa recti suis D8 22.0 mg, Mucosa vesicae felleae suis D8 22.0 mg, Mucosa vesicae urinae suis D8 22.0 mg, Oxalis acetosella D6 22.0 mg, Pankreas suis D10 22.0 mg, Phosphorus D8 22.0 mg, Psychotria ipecacuanha D8 22.0 mg, Pulsatilla pratensis D6 22.0 mg, Semecarpus anacardium D6 22.0 mg, Strychnos nux-vomica D13 22.0 mg, Sulfur D8 22.0 mg, Ventriculus suis D8 22.0 mg, Veratrum album D4 22.0 mg, Natrium diethylxalacetatum D8 22.0 mg. Excipients: Sodium chloride 19.1 mg, water for injections 1430.0 mg. **Indications:** **Tablets, injection solution:** Disorders of mucous membranes (gastro-intestinal, respiratory and genitourinary system and the eye). **Contraindications:** **Tablets, injection solution:** Known allergy (hypersensitivity) to one or more of the ingredients. **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. **Injection solution:** None. **Side effects:** **Tablets, injection solution:** None have been reported. **Interactions with other medication:** **Tablets, injection solution:** No interactions have been reported, and none are expected due to the homeopathic dilutions. **Pregnancy and lactation:** **Tablets, injection solution:** For this product no clinical data on pregnancy and lactation are available. Homeopathic dilutions of the substances present in this medicament are not known to be toxic during pregnancy and lactation. No adverse effects have so far been reported. **Effects on ability to drive and use machines:** **Tablets, injection solution:** No effects on the ability to drive and use machines have been reported, and none are expected due to the homeopathic dilutions. **Dosage:** **Tablets: Standard dosage:** Adults (and children 12 yrs. and older): 1 tablet 3x daily. **Pediatric:** Below 2 yrs.: 1 tablet 1x daily. 2–5 yrs.: 1 tablet 1–2x daily. 6–11 yrs.: 1 tablet 2x daily. **Acute or initial dosage:** Adults (and children 12 yrs. and older): 1 tablet every 1/2 to 1 hr., up to 12x daily, and then continue with standard dosage. **Pediatric:** Below 2 yrs.: 1 tablet every 1 to 2 hrs., up to 4x daily, and then continue with standard dosage. 2–5 yrs.: 1 tablet every 1 to 2 hrs., up to 6x daily, and then continue with standard dosage. 6–11 yrs.: 1 tablet every 1 to 2 hrs., up to 8x 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. **Injection solution: Standard dosage:** Adults (and children 12 yrs. and older): 1 ampoule 1 to 3x weekly. **Pediatric:** 2–5 yrs.: 1/2 ampoule 1 to 3x weekly. 6–11 yrs.: 2/3 of an ampoule 1 to 3x 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.: ½ 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:** Mucosa comp.-Heel, Solution for injection may be administered by the s.c., i.d., i.m. or i.v. route. **Overdose: Tablets, injection solution:** No cases of overdose have been reported, and none are expected due to the homeopathic dilutions. **Package sizes: Tablets:** Packs containing 50, 100 and 250 tablets. **Injection solution:** Packs containing 5, 10, 50 and 100 ampoules of 2.2 ml each.

### Tonsilla compositum Summary of Product Characteristics

#### Oral drops · Injection solution

**Compositions:** Oral drops: 100 g contain: Active ingredients: Acidum ascorbicum D6 3.0 g, Acidum L(+)-lacticum D6 3.0 g, Aesculus hippocastanum D6 3.0 g, Barium carbonicum D28 3.0 g, Calcium phosphoricum D10 3.0 g, Conium maculatum D12 3.0 g, Cortex glandulae suprarenalis suis D13 3.0 g, Cortisonum aceticum D13 3.0 g, Dactylopius coccus D6 3.0 g, Echinacea angustifolia D4 3.0 g, Embryo totalis suis D13 3.0 g, Ferrum phosphoricum D10 3.0 g, Funiculus umbilicalis suis D10 3.0 g, Galium aparine D6 3.0 g, Gentiana lutea D6 3.0 g, Geranium robertianum D6 3.0 g, Hepar suis D10 3.0 g, Hypothalamus suis D10 3.0 g, Kallium stibyltartaricum D6 3.0 g, Levothyroxinum D13 3.0 g, Medulla ossis suis D10 3.0 g, Mercurius solubilis Hahnemanni D13 3.0 g, Nodus lymphaticus suis D8 3.0 g, Pulsatilla pratensis D6 3.0 g, Solanum dulcamara D4 3.0 g, Spleen suis D10 3.0 g, Sulfur D8 3.0 g, Tonsilla suis D28 3.0 g. Excipients: Ethanol (96 per cent) 0.3 g; water, purified 15.7 g. **Injection solution:** 1 ampoule (2.2 g) contains: Active ingredients: Acidum ascorbicum D6 22.0 mg, Acidum L(+)-lacticum D6 22.0 mg, Aesculus hippocastanum D6 22.0 mg, Barium carbonicum D28 22.0 mg, Calcium phosphoricum D10 22.0 mg, Conium maculatum D4 22.0 mg, Cortex glandulae suprarenalis suis D13 22.0 mg, Cortisonum aceticum D13 22.0 mg, Dactylopius coccus D6 22.0 mg, Echinacea D4 22.0 mg, Embryo totalis suis D13 22.0 mg, Ferrum phosphoricum D10 22.0 mg, Funiculus umbilicalis suis D10 22.0 mg, Galium aparine D6 22.0 mg, Gentiana lutea D6 22.0 mg, Geranium robertianum D6 22.0 mg, Hepar suis D10 22.0 mg, Hypothalamus suis D10 22.0 mg, Kallium stibyltartaricum D6 22.0 mg, Levothyroxinum D13 22.0 mg, Medulla ossis suis D10 22.0 mg, Mercurius solubilis Hahnemanni D13 22.0 mg, Nodus lymphaticus suis D8 22.0 mg, Pulsatilla pratensis D6 22.0 mg, Solanum dulcamara D4 22.0 mg, Spleen suis D10 22.0 mg, Sulfur D8 22.0 mg, Tonsilla suis D28 22.0 mg. Excipients: Sodium chloride 19.2 mg, water for injections 1540 mg. **Indications:** Oral drops, injection solution: Stimulation of the body defenses including the lymphatic immune system in acute, recurrent and chronic disorders, e.g. tonsillitis, recurrent infections. **Contraindications:** Oral drops, injection solution: Known allergy (hypersensitivity) to one or more of the ingredients. Special warnings and special precautions for use: Oral drops: This medicinal product contains 35 vol.-% ethanol (alcohol). Injection solution: None. **Side effects:** Oral drops: Like all medicinal products, homeopathic medicines can cause side effects in isolated cases, such as transient allergic reactions. The frequency of these effects is not known. Injection solution: None have been reported. **Interactions with other medication:** Oral drops, injection solution: No interactions have been reported, and none are expected due to the homeopathic dilutions. **Pregnancy and lactation:** Drops, injection solution: For this product no clinical data on pregnancy and lactation are available. Homeopathic dilutions of the substances present in this medicament are not known to be toxic during pregnancy and lactation. No adverse effects have so far been reported. **Effects on ability to drive and use machines:** Oral drops, injection solution: No effects on the ability to drive and use machines have been reported, and none are expected due to the homeopathic dilutions. **Dosage: Oral drops: Standard dosage:** Adults (and children 12 yrs. and older): 10 drops 3x daily. Pediatric: Below 2 yrs.: 3 drops 3x daily. 2–5 yrs.: 5 drops 3x daily. 6–11 yrs.: 7 drops 3x daily. **Acute or initial dosage:** Adults (and children 12 yrs. and older): 10 drops every ½ to 1 hr., up to 12x daily, and then continue with standard dosage. Pediatric: Below 2 yrs.: 3 drops every ½ to 1 hr., up to 12x daily, and then continue with standard dosage. 2–5 yrs.: 5 drops every ½ to 1 hr., up to 12x daily, and then continue with standard dosage. 6–11 yrs.: 7 drops every ½ to 1 hr., up to 12x 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. Injection solution: Standard dosage: Adults (and children 12 yrs. and older): 1 ampoule 1 to 3x weekly. Pediatric: 2–5 yrs.: ½ ampoule 1 to 3x weekly. 6–11 yrs.: ⅔ of an ampoule 1 to 3x 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.: ½ 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:** Tonsilla comp., Solution for injection may be administered by the s.c., i.d., i.m. or i.v. route. **Overdose:** Oral drops, injection solution: No cases of overdose have been reported, and none are expected due to the homeopathic dilutions. **Package sizes:** Oral drops (65636): Packs containing 30 ml and 100 ml. Injection solution (9483): Packs containing 5, 10, 50 and 100 ampoules of 2.2 ml each.

### Neurexan Summary of Product Characteristics

#### Tablets · Oral drops

**Compositions: Tablets:** 1 tablet = 301.5 mg containing: Active ingredients: Avena sativa D2 0.6 mg, Coffea arabica D12 0.6 mg, Passiflora incarnata D2 0.6 mg, Zincum isovalerianicum D4 0.6 mg. Excipients: Lactose monohydrate 3.0 mg, Magnesium stearate 1.5 mg. Oral drops: 100 g containing: Active ingredients: Avena sativa D2 0.06 g, Coffea arabica D12 0.06 g, Passiflora incarnata D2 0.06 g, Zincum isovalerianicum D4 0.06 g. Excipients: Ethanol 96% (V/V) 31.34 g; water, purified 68.42 g. **Indications: Tablets, oral drops:** Nervous restlessness and sleep disturbances. **Contraindications: Tablets, oral drops:** Known allergy (hypersensitivity) to one or more of the ingredients. **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. **Oral drops:** This medicinal product contains 36 vol.-% ethanol (alcohol). Side effects: Tablets: Allergic (hypersensitivity) skin reactions may occur in very rare cases (i.e. affects less than 1 in 10,000 users). Due to the homeopathic nature of Neurexan tablets a temporary worsening in symptoms (initial aggravation) is possible but harmless. Oral drops: Due to the homeopathic nature of Neurexan drops a temporary worsening in symptoms (initial aggravation) is possible but harmless. **Interactions with other medication: Tablets, oral drops:** No interactions have been reported, and none are expected due to the homeopathic dilutions. **Pregnancy and lactation: Tablets, oral drops:** For this product no clinical data on pregnancy and lactation are available. Homeopathic dilutions of the substances present in this medicament are not known to be toxic during pregnancy and lactation. No adverse effects have so far been reported. **Effects on ability to drive and use machines: Tablets, oral drops:** No effects on the ability to drive and use machines have been reported, and none are expected due to the homeopathic dilutions. **Dosage: Tablets: Standard dosage:** Adults (and children 12 yrs. and older): 1 tablet 3x daily. Pediatric: Below 2 yrs.: 1 tablet 1x daily. 2–5 yrs.: 1 tablet 1–2x daily. 6–11 yrs.: 1 tablet 2x daily. **Acute or initial dosage:** Adults (and children 12 yrs. and older): 1 tablet every ½ to 1 hr., up to 12x daily, and then continue with standard dosage. Pediatric: Below 2 yrs.: 1 tablet every 1 to 2 hrs., up to 4x daily, and then continue

with standard dosage. 2–5 yrs.: 1 tablet every 1 to 2 hrs., up to 6x daily, and then continue with standard dosage. 6–11 yrs.: 1 tablet every 1 to 2 hrs., up to 8x 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. Oral drops: Standard dosage: Adults (and children 12 yrs. and older): 10 drops 3x daily. Pediatric: Below 2 yrs.: 3 drops 3x daily. 2–5 yrs.: 5 drops 3x daily. 6–11 yrs.: 7 drops 3x daily. Acute or initial dosage: Adults (and children 12 yrs. and older): 10 drops every ½ to 1 hr., up to 12x daily, and then continue with standard dosage. Pediatric: Below 2 yrs.: 3 drops every ½ to 1 hr., up to 12x daily, and then continue with standard dosage. 2–5 yrs.: 5 drops every ½ to 1 hr., up to 12x daily, and then continue with standard dosage. 6–11 yrs.: 7 drops every ½ to 1 hr., up to 12x 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. **Overdose: Tablets, oral drops:** No cases of overdose have been reported, and none are expected due to the homeopathic dilutions. **Package sizes: Tablets (9519):** Packs containing 50, 100 and 250 tablets. Oral drops (9880): Packs containing 30 ml and 100 ml.

### Spascupreel Summary of Product Characteristics

#### Tablets · Injection solution

**Compositions: Tablets:** 1 tablet = 301.5 mg containing: Active ingredients: Aconitum napellus D6 60 mg, Amanita muscaria D4 15 mg, Ammonium bromatum Trit. D4 30 mg, Atropinum sulfuricum D6 30 mg, Citrullus colocynthis D4 30 mg, Cuprum sulfuricum D6 15 mg, Gelsemium sempervirens D6 30 mg, Magnesium phosphoricum D6 30 mg, Matricaria recutita D3 15 mg, Passiflora incarnata D2 15 mg, Veratrum album D6 30 mg. Excipients: Magnesium stearate 1.5 mg; contains lactose. Injection solution: 1 ampoule (1.1 g) contains: Active ingredients: Aconitum napellus D6 2.20 mg, Amanita muscaria D4 0.55 mg, Ammonium bromatum D4 1.10 mg, Atropinum sulfuricum D6 1.10 mg, Citrullus colocynthis D4 1.10 mg, Cuprum sulfuricum D6 0.55 mg, Gelsemium sempervirens D6 1.10 mg, Magnesium phosphoricum D6 1.10 mg, Matricaria recutita D3 0.55 mg, Passiflora incarnata D2 0.55 mg, Veratrum album D6 1.10 mg. Excipients: Sodium chloride 10.4 mg, water for injections 1089.0 mg. Suppositories: 1 suppository = 2.0 g containing: Active ingredients: Aconitum napellus D5 2.20 mg, Amanita muscaria D3 0.55 mg, Ammonium bromatum D3 1.10 mg, Atropinum sulfuricum D5 1.10 mg, Citrullus colocynthis D3 1.10 mg, Cuprum sulfuricum D5 0.55 mg, Gelsemium sempervirens D5 1.10 mg, Magnesium phosphoricum D6 1.10 mg, Matricaria recutita D2 0.55 mg, Passiflora incarnata D1 0.55 mg, Veratrum album D5 1.10 mg. Excipients: Hard fat 1989.0 mg. **Indications: Tablets, Injection solution:** Spasms of the smooth musculature of the gastrointestinal and the urogenital tract. **Contraindications: Tablets, Injection solution:** Known allergy (hypersensitivity) to one or more of the ingredients. **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. **Injection solution:** None. **Side effects: Tablets:** Like all medicinal products, homeopathic medicines may cause side effects. In isolated cases transient allergies (e.g. urticaria, pruritus) as well as nausea have been reported. The frequency of these effects is not known. **Injection solution:** Like all medicinal products, homeopathic medicines can cause side effects in isolated cases, such as transient allergic reactions. The frequency of these effects is not known. **Interactions with other medication: Tablets, Injection solution:** No interactions have been reported, and none are expected due to the homeopathic dilutions. **Pregnancy and lactation: Tablets, Injection solution:** For this product no clinical data on pregnancy and lactation are available. Homeopathic dilutions of the substances present in this medicament are not known to be toxic during pregnancy and lactation. No adverse effects have so far been reported. **Effects on ability to drive and use machines: Tablets, Injection solution:** No effects on the ability to drive and use machines have been reported, and none are expected due to the homeopathic dilutions. **Dosage: Tablets: Standard dosage:** Adults (and children 12 yrs. and older): 1 tablet 3x daily. Below 2 yrs.: 1 tablet 1x daily. 2–5 yrs.: 1 tablet 1–2x daily. 6–11 yrs.: 1 tablet 2x daily. **Acute or initial dosage:** Adults (and children 12 yrs. and older): 1 tablet every ½ to 1 hr., up to 12x daily, and then continue with standard dosage. Below 2 yrs.: 1 tablet every 1 to 2 hrs. up to 4x daily, and then continue with standard dosage. 2–5 yrs.: 1 tablet every 1 to 2 hrs. up to 6x daily, and then continue with standard dosage. 6–11 yrs.: 1 tablet every 1 to 2 hrs. up to 8x 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. **Injection solution: Standard dosage:** Adults (and children 12 yrs. and older): 1 ampoule 1 to 3x weekly. 2–5 yrs.: ½ ampoule 1 to 3x weekly. 6–11 yrs.: ⅔ of an ampoule 1 to 3x weekly. **Acute or initial dosage:** Adults (and children 12 yrs. and older): 1 ampoule daily, and then continue with standard dosage. 2–5 yrs.: ½ 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:** Spascupreel, Solution for injection may be administered by the s.c., i.d., i.m. or i.v. route. **Overdose:** Tablets, Injection solution: No cases of overdose have been reported, and none are expected due to the homeopathic dilutions. **Package sizes: Tablets (9749):** Packs containing 50 and 250 tablets. Injection solution (8558): packs containing 10 and 100 ampoules of 1.1ml each.

### Traumeel® Summary of Product Characteristics

#### Tablets · Injection solution · Ointment

**Compositions: Tablets:** 1 tablet = 301.5 mg containing: Active ingredients: Atropa belladonna D4 75 mg; Aconitum napellus D3, Hepar sulfuris D8, Mercurius solubilis Hahnemanni D8, 30 mg each; Chamomilla recutita D3, Symphytum officinale D8 24 mg each; Achillea millefolium D3, Arnica montana D2, Calendula officinalis D2, Hamamelis virginiana D2, 15 mg each; Bellis perennis D2, Echinacea angustifolia D2, Echinacea purpurea D2 6 mg each; Hypericum perforatum D2 3 mg. Excipients: Lactose monohydrate 6.0 mg; Magnesium stearate 1.5 mg. **Injection solution:** 2.2 g containing: Active ingredients: Achillea millefolium D3, Arnica montana D2, Atropa belladonna D2, Calendula officinalis D2, Hepar sulfuris D6, Chamomilla recutita D3, Symphytum officinale D6, 2.2 mg each; Aconitum napellus D2 1.32 mg; Bellis perennis D2 1.1 mg; Mercurius solubilis Hahnemanni D6 1.1 mg; Hypericum perforatum D2 0.66 mg; Echinacea angustifolia D2, Echinacea purpurea D2 0.55 mg each; Hamamelis virginiana D1 0.22 mg. Excipients: Sodium chloride 19.4 mg, water for injections 2179.1 mg. **Ointment:** 100 g containing: Active ingredients: Arnica montana D3 1.500 g; Calendula officinalis D0, Hamamelis virginiana D0, 0.450 g each; Chamomilla recutita D0, Echinacea angustifolia D0, Echinacea purpurea D0, 0.150 g each; Bellis perennis D0, Symphytum officinale D4, 0.100 g each; Achillea millefolium D0, Hypericum perforatum D6 0.090 g each; Aconitum napellus D1, Atropa belladonna D1, 0.050 g each; Mercurius solubilis Hahnemanni D6 0.040 g; Hepar sulfuris D6, 0.025 g. Excipients: Paraffin, liquid 9.342 g; cetostearyl alcohol (type A), emulsifying 8.007 g; white soft paraffin 9.342 g; water, purified 60.579 g; ethanol 96% (V/V) 9.335 g. **Indications: Tablets, injection solution, ointment:** Traumatic injuries of all kinds such as sprains, dislocations, contusions, haemarthrosis and effusions into a joint; regulation of inflammatory processes in various organs and tissues, including in particular acute and chronic/degenerative disorders of the

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musculoskeletal system. **Contraindications:** **Tablets, injection solution:** 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), Matricaria 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. **Injection solution:** None. **Ointment:** Cetylstearyl alcohol may cause local skin reactions (e.g. contact dermatitis). Avoid contact with eyes, mucosae, open wounds or broken skin. **Side effects:** **Tablets, ointment:** Allergic (hypersensitivity) skin reactions may occur in very rare cases (i.e. affects less than 1 in 10,000 users). **Injection solution:** Allergic (hypersensitivity) reactions (e.g. skin allergies, redness/swelling at the injection site, even up to anaphylaxis) may occur in very rare cases (i.e. affects less than 1 in 10,000 users). **Interactions with other medication:** **Tablets, injection solution, ointment:** No interactions have been reported, and none are expected due to the homeopathic dilutions. **Pregnancy and lactation:** **Tablets, injection solution, ointment:** For this product no clinical data on pregnancy and lactation are available. Homeopathic dilutions of the substances present in this medicament are not known to be toxic during pregnancy and lactation. No adverse effects have so far been reported. **Effects on ability to drive and use machines:** **Tablets, injection solution:** No effects on the ability to drive and use machines have been reported, and none are expected due to the homeopathic dilutions. **Ointment:** Not applicable. **Dosage:** **Tablets: Standard dosage:** Adults (and children 12 yrs. and older): 1 tablet 3x daily; 6–11 yrs.: 1 tablet 2x daily; 2–5 yrs.: 1 tablet 1–2x daily; below 2 yrs.: 1 tablet 1x daily. **Acute or initial dosage:** Adults (and children 12 yrs. and older): 1 tablet every ½ to 1 hr., up to 12x daily, and then continue with standard dosage; 6–11 yrs.: 1 tablet every 1 to 2 hrs., up to 8x daily, and then continue with standard dosage; 2–5 yrs.: 1 tablet every

1 to 2 hrs., up to 6x daily, and then continue with standard dosage; below 2 yrs.: 1 tablet every 1 to 2 hrs., up to 4x 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. **Injection solution: Standard dosage:** Adults (and children 12 yrs. and older): 1 ampoule 1 to 3x weekly. 6–11 yrs.: ⅔ of an ampoule 1 to 3x weekly; 2–5 yrs.: ½ ampoule 1 to 3x weekly. **Acute or initial dosage:** Adults (and children 12 yrs. and older): 1 ampoule daily, and then continue with standard dosage; 6–11 yrs.: ⅔ of an ampoule daily, and then continue with standard dosage; 2–5 yrs.: ½ ampoule daily, and then continue with standard dosage. **Method of administration:** Solution for injection may be administered by the s.c., i.d., i.m., i.a. or i.v. route. **Ointment: Standard dosage:** Apply 2x 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. **Overdose: Tablets, injection solution:** No cases of overdose have been reported, and none are expected due to the homeopathic dilutions. **Ointment:** No cases of overdose have been reported, and none are expected due to the homeopathic dilutions and external use. **Package sizes: Tablets (9753):** Packs containing 50 and 250 tablets. **Injection solution (8651):** Packs containing 10 and 100 ampoules of 2.2 ml each. **Ointment (9578):** Tubes containing 50 and 100 g of ointment.

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