Patient information leaflet

Pasiënt-inligtingstuk 015231/5008/ZA

**Scheduling status**
Schedule 0

**Skeduleringstatus**
Skedule 0

**Proprietary name, strength and pharmaceutical form**

**Handelsnaam, sterkte en farmaseutiese vorm**

# Traumeel® S

## Tablets / Tablette

**Read all of this leaflet carefully because it contains important information for you**
Traumeel® S is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use Traumeel® S carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share Traumeel® S with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

**Lees die hele inligtingstuk noukeurig aangesien dit belangrike inligting bevat**
Traumeel® S is sonder 'n doktersvoorskrif beskikbaar om 'n ligte siektetoestand te behandel. Nogtans moet Traumeel® S versigtig gebruik word om die beste resultate te verkry.
- Hou hierdie inligtingstuk. U mag dit weer moet lees.
- Moenie Traumeel® S met enige ander persoon deel nie.
- Vra u apteker indien u meer inligting of advies benodig.
- U moet 'n geneesheer raadpleeg indien u simptome vererger of nie verbeter nie.

## 1. What Traumeel® S contains

1 tablet contains:
The active substances are: Arnica montana D2 15 mg, Calendula officinalis D2 15 mg, Hamamelis virginiana D2 15 mg, Achillea millefolium D3 15 mg, Atropa belladonna D4 75 mg, Aconitum napellus D3 30 mg, Mercurius solubilis Hahnemanni D8 30 mg, Hepar sulfuris D8 30 mg, Chamomilla recutita D3 24 mg, Symphytum officinale D8 24 mg, Bellis perennis D2 6 mg, Echinacea angustifolia D2 6 mg, Echinacea purpurea D2 6 mg, Hypericum perforatum D2 3 mg.
The other ingredients are: lactose monohydrate (approx. 300 mg), magnesium stearate.

## 1. Wat Traumeel® S bevat

1 tablet bevat:
Die aktiewe bestanddele is: Arnica montana D2 15 mg, Calendula officinalis D2 15 mg, Hamamelis virginiana D2 15 mg, Achillea millefolium D3 15 mg, Atropa belladonna D4 75 mg, Aconitum napellus D3 30 mg, Mercurius solubilis Hahnemanni D8 30 mg, Hepar sulfuris D8 30 mg, Chamomilla recutita D3 24 mg, Symphytum officinale D8 24 mg, Bellis perennis D2 6 mg, Echinacea angustifolia D2 6 mg, Echinacea purpurea D2 6 mg, Hypericum perforatum D2 3 mg.
Die ander bestanddele is: laktosemonohidraat (ongeveer 300 mg), magnesiumstearaat.

## 2. What Traumeel® S is used for

Pharmacological classification:
D. 33.2. Homeopathy.
Discipline of the medicine: Homeopathy

Traumeel® S is prepared in accordance with homeopathic principles and is proposed for the treatment of sprains, strains, fractures, post-operative and post-traumatic swelling of soft tissues, inflammation of various organs and tissues, including, in particular, the musculoskeletal system e.g. tenosynovitis, bursitis, styloiditis, epicondylitis, periarthritis, arthrosis.

## 2. Waarvoor Traumeel® S gebruik word

Farmakologiese klassifikasie:
D. 33.2. Homeopatie.
Dissipline van die medisyne: Homeopatie

Traumeel® S is voorberei volgens homeopatiese beginsels en word aangedui vir die behandeling van alle tipes verstuitings, ontwrigtings, kneusings en frakture, post-operatiewe en post-traumatiese swelling van sagte weefsel, inflammasie van verskeie organe en weefsel, in die besonder, die muskuloskeletale stelsel bv. tenosynovitis, bursitis, stiloiditis, epikondilitis, periartritis en artrose.

## 3. Before you take Traumeel® S

### Do not take Traumeel® S:
- if you are hypersensitive (allergic) to
  - active substances or any of the other ingredients of Traumeel® S
  - plants of the Compositae (daisy) family
- Principally contraindicated for patients with progressive systemic disease such as tuberculosis, leukose, collagen disorders, multiple sclerosis, AIDS, HIV infection, and other autoimmune disorders.

### Pregnancy and breastfeeding
If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

### Important information about some of the ingredients of Traumeel® S:
This preparation contains natural lactose. Although the quantity of lactose present is probably not sufficient to cause discomfort, a health professional should be consulted in strong cases of lactose intolerance. A temporary aggravation of the existing symptoms is possible after taking a homeopathic preparation.

### Taking other medicines with Traumeel® S:
If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of Traumeel® S with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

## 3. Voordat u Traumeel® S gebruik

### Moenie Traumeel® S gebruik:
- indien u hipersensitief (allergies) is vir
  - die aktiewe bestanddele of enige van die ander bestanddele van Traumeel® S
  - die plante van die Compositae familie.
- In beginsel teenaangedui vir pasiënte met progressiewe sistemiese siektes soos tuberkulose, leukose, kollageenversteurings, veelvuldige sklerose, VIGS, HIV infeksie en ander outoimmuunversteurings.

### Swangerskap en borsvoeding
Indien u swanger is of u baba borsvoed, raadpleeg u geneesheer, apteker of ander gesondheidswerker vir advies voordat u hierdie medisyne neem.

### Belangrike inligting omtrent sommige van die bestanddele van Traumeel® S:
Hierdie preparaat bevat natuurlike laktose. Hoewel die hoeveelheid laktose waarskynlik nie genoegsaam is om ongemak te veroorsaak nie moet 'n professsionele gesondheidswerker geraadpleeg te word in sterk gevalle van laktose-intoleransie. 'n Tydelike verergering van die bestaande simptome is moontlik na die neem van 'n homeopatiese preparaat.

### Die neem van ander medisyne saam met Traumeel® S:
Indien u op 'n gereelde basis ander medisyne neem, insluitend komplementêre of tradisionele medisyne, mag die gebruik van Traumeel® S saam met hierdie medisyne ongewenste interaksies veroorsaak.
Raadpleeg asseblief u geneesheer, apteker of ander professionele gesondheidswerker vir advies.

## 4. How to take Traumeel® S

Do not share medicines prescribed for you with any other person.
Always take Traumeel® S exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:
Adults and children over 3 years of age: Dissolve 1 tablet in the mouth 3 times daily.
Infants: Half the adult dose.

### If you take more Traumeel® S than you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

### If you forget to take Traumeel® S:
Do not take a double dose to make up for forgotten individual doses.

## 4. Hoe om Traumeel® S te neem

Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.
Neem Traumeel® S presies soos wat u geneesheer dit voorgeskryf het. U moet u geneesheer of apteker raadpleeg indien u onseker is.

Die gewone dosis is:
Volwassenes en kinders bo 3 jaar: Los een tablet in die mond op 3 maal per dag. Babas: Die helfte van die volwasse dosis.

### Indien u meer Traumeel® S neem as wat u moet:
In die geval van oordosering, raadpleeg u geneesheer of apteker. Indien nie een van hulle beskikbaar is nie, soek hulp by die naaste hospitaal of gifbeheersentrum.

### Indien u vergeet om Traumeel® S te neem:
Moenie 'n dubbeldosis neem om op te maak vir die vergete individuele dosisse nie.

## 5. Possible side effects

Traumeel® S can have side effects.
Increased flow of saliva may occur after taking this medication; in such an event, do not continue therapy with this preparation. Hypersensitivity reactions may occur in individual cases. The following have been observed among patients taking medication containing preparations from rudbeckia: rashes, itching, facial swelling (rare), acute respiratory distress, vertigo, and acute hypotension.
Not all side effects reported for Traumeel® S are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## 5. Moontlike newe-effekte

Traumeel® S kan newe-effekte hê.
Verhoogde speekselvloei mag voorkom na die inname van hierdie medikasie; in so 'n geval moet terapie met hierdie preparaat gestaak word. Hipersensitiwiteitsreaksies mag in individuele gevalle voorkom. Die volgende is by pasiënte waargeneem wat medikasie neem wat preparate van rudbeckia bevat: veluitslag, jeuk, gesigswelling (seldsaam), akute respiratoriese nood, duiseligheid en akute hipotensie.
Nie alle newe-effekte wat vir Traumeel® S gerapporteer is word in hierdie inligtingstuk ingesluit nie. Indien u algemene gesondheidstoestand vererger terwyl u hierdie medikasie neem, raadpleeg u geneesheer, apteker of ander professionele gesondheidswerker vir advies. Indien u enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief u geneesheer of apteker in kennis.

## 6. Storing and disposing of Traumeel® S

Keep all medicines out of the reach and sight of children.
- Store in a cool (below 25 °C) dry place.

## 6. Opberging van en beskikking oor Traumeel® S

Hou alle medisyne buite die bereik en sig van kinders.
- Bêre in 'n koel (onder 25 °C) droë plek.

## 7. Presentation of Traumeel® S

Containers of 50 and 250 tablets.

## 7. Aanbieding van Traumeel® S

Houers van 50 en 250 tablette.

## 8. Identification of Traumeel® S

White to light yellow tablets, sometimes small orange dots.

## 8. Identifikasie van Traumeel® S

Wit tot liggeel tablette, soms klein oranje spikkels.

## 9. Registration number / Reference number

U 5514 (Act 101/1965)

## 9. Registrasienommer / Verwysingsnommer

U 5514 (Wet 101/1965)

## 10. Name and business address of the holder of the certificate of registration

ModHomCo (Pty) Ltd
96 Amsterdam Street
Clubview, 0157 Centurion

## 10. Naam en besigheidsadres van die houer van die registrasiesertifikaat

ModHomCo (Edms) Bpk
Amsterdamstraat 96
Clubview, 0157 Centurion

## 11. Date of publication

October 2023

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

## 11. Datum van publikasie

Oktober 2023

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA vir kwaliteit, veiligheid of beoogde gebruik geëvalueer nie.

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Professional Information

Professionele Inligting

# Traumeel® S

## Tablets / Tablette

## 1. Scheduling status

Schedule 0

## 1. Skeduleringstatus

Skedule 0

## 2. Proprietary name and dosage form

Traumeel® S Tablets

## 2. Handelsnaam en doseervorm

Traumeel® S Tablette

## 3. Composition

1 tablet contains: Arnica montana D2 15 mg, Calendula officinalis D2 15 mg, Hamamelis virginiana D2 15 mg, Achillea millefolium D3 15 mg, Atropa belladonna D4 75 mg, Aconitum napellus D3 30 mg, Mercurius solubilis Hahnemanni D8 30 mg, Hepar sulfuris D8 30 mg, Chamomilla recutita D3 24 mg, Symphytum officinale D8 24 mg, Bellis perennis D2 6 mg, Echinacea angustifolia D2 6 mg, Echinacea purpurea D2 6 mg, Hypericum perforatum D2 3 mg.
Excipients: approx. 300 mg lactose monohydrate, magnesium stearate.

## 3. Samestelling

1 tablet bevat: Arnica montana D2 15 mg, Calendula officinalis D2 15 mg, Hamamelis virginiana D2 15 mg, Achillea millefolium D3 15 mg, Atropa belladonna D4 75 mg, Aconitum napellus D3 30 mg, Mercurius solubilis Hahnemanni D8 30 mg, Hepar sulfuris D8 30 mg, Chamomilla recutita D3 24 mg, Symphytum officinale D8 24 mg, Bellis perennis D2 6 mg, Echinacea angustifolia D2 6 mg, Echinacea purpurea D2 6 mg, Hypericum perforatum D2 3 mg.
Bymiddels: ongeveer 300 mg laktosemonohidraat, magnesiumstearaat.

## 4. Pharmacological classification

D. 33.2. Homeopathy.

## 4. Farmakologiese klassifikasie

D. 33.2. Homeopatie.

## 5. Pharmacological action

Action based on homeopathic principles.

## 5. Farmakologiese werking

Werking gebaseer op homeopatiese beginsels.

## 6. Indications

Traumeel® S is prepared in accordance with homeopathic principles and is proposed for the treatment of sprains, strains, fractures, post-operative and post-traumatic swelling of soft tissues, inflammation of various organs and tissues, including, in particular, the musculoskeletal system e.g. tenosynovitis, bursitis, styloiditis, epicondylitis, periarthritis, arthrosis.

## 6. Indikasies

Traumeel® S is voorberei volgens homeopatiese beginsels en word aangedui vir die behandeling van alle tipes verstuitings, ontwrigtings, kneusings en frakture, post-operatiewe en post-traumatiese swelling van sagte weefsel, inflammasie van verskeie organe en weefsel, in die besonder, die muskuloskeletale stelsel bv. tenosynovitis, bursitis, stiloiditis, epikondilitis, periartritis en artrose.

## 7. Contraindications

Hypersensitivity to any of the ingredients, including excipients, or hypersensitivity to members of the Compositae family. Principally contraindicated for patients with progressive systemic disease such as tuberculosis, leukose, collagen disorders, multiple sclerosis, AIDS, HIV infection, and other autoimmune disorders.

## 7. Kontra-indikasies

Hipersensitiwiteit vir enige van die bestanddele, insluitend bymiddels, of hipersensitiwiteit vir plante van die daisie (madeliefie) (compositae) familie. In beginsel teenaangedui vir pasiënte met progressiewe sistemiese siektes soos tuberkulose, leukose, kollageenversteurings, veelvuldige sklerose, VIGS, HIV infeksie en ander outo-immuunversteurings.

## 8. Warnings

This preparation contains natural lactose. Although the quantity of lactose present is probably not sufficient to cause discomfort, a health professional should be consulted in strong cases of lactose intolerance. A temporary aggravation of the existing symptoms is possible after taking a homeopathic preparation.

## 8. Waarskuwings

Hierdie preparaat bevat natuurlike laktose. Hoewel die hoeveelheid laktose aanwesig waarskynlik nie genoegsaam is om ongemak te veroorsaak nie moet 'n professionele gesondheidswerker in erge gevalle van laktose-intoleransie geraadpleeg word. 'n Tydelike verergering van die bestaande simptome is moontlik na die neem van 'n homeopatiese preparaat.

## 9. Interactions

No interactions studies have been performed.

## 9. Interaksies

Geen interaksie-studies is uitgevoer nie.

## 10. Pregnancy and lactation

Safety and/or efficacy has not been established.

## 10. Swangerskap en borsvoeding

Veiligheid en/of doeltreffendheid is nie vasgestel nie.

## 11. Dosage and directions for use

Adults and children over 3 years of age: Dissolve 1 tablet in the mouth 3 times daily.
Infants: Half the adult dose.

## 11. Dosering en gebruiksaanwysings

Volwassenes en kinders bo 3 jaar: Los een tablet in die mond op 3 maal per dag.
Babas: Die helfte van die volwasse dosis.

## 12. Side effects and special precautions

### 12.1 Side effects

Increased flow of saliva may occur after taking this medication; in such an event, do not continue therapy with this preparation. Hypersensitivity reactions may occur in individual cases.
The following have been observed among patients taking medication containing preparations from rudbeckia: rashes, itching, facial swelling (rare), acute respiratory distress, vertigo, and acute hypotension.

### 12.2 Special precautions

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### 12.3 Effects on ability to drive and use machines

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## 12. Newe-effekte en spesiale voorsorgmaatreëls

### 12.1 Newe-effekte

Verhoogde speekselvloei mag voorkom na die neem van hierdie medikasie; in so 'n geval moet terapie met hierdie preparaat gestaak word. Hipersensitiwiteitsreaksies mag in individuele gevalle voorkom.
Die volgende is onder pasiënte opgemerk wat medikasie neem wat preparate van rudbeckia bevat: veluitslag, jeuk, gesigswelling (seldsaam), akute respiratoriese nood, duiseligheid en akute hipotensie.

### 12.2 Spesiale voorsorgmaatreëls

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### 12.3 Effekte op die vermoë om voertuie te bestuur en masjinerie te gebruik

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## 13. Known symptoms of overdosage and particulars of its treatment

None known.

## 13. Bekende simptome van oordosering en besonderhede van die behandeling daarvan

Geen bekend nie.

## 14. Identification

White to light yellow tablets, sometimes small orange dots.

## 14. Identifikasie

Wit tot liggeel tablette, soms klein oranje spikkels.

## 15. Presentation

Containers of 50 and 250 tablets.

## 15. Aanbieding

Houers van 50 en 250 tablette.

## 16. Storage instructions

Store in a cool (below 25 °C) dry place beyond the reach of children.

## 16. Opbergingsinstruksies

Hou in 'n koel (onder 25 °C) droë plek buite die bereik van kinders.

## 17. Registration number

U 5514 (Act 101/1965)

## 17. Registrasienommer

U 5514 (Wet 101/1965)

## 18. Name and business address of the holder of the certificate of registration

ModHomCo (Pty) Ltd
96 Amsterdam Street
Clubview, 0157 Centurion
**Manufactured in Germany.**

## 18. Naam en besigheidsadres van die houer van die registrasiesertifikaat

ModHomCo (Edms) Bpk
Amsterdamstraat 96
Clubview, 0157 Centurion
**Vervaardig in Duitsland.**

## 19. Date of publication of the professional information

October 2023

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

## 19. Datum van publikasie van hierdie professionele inligting

Oktober 2023

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA vir kwaliteit, veiligheid of beoogde gebruik geëvalueer nie.

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