

Patient information leaflet

#### Scheduling status

Schedule 0

Proprietary name, strength and pharmaceutical form

# Traumeel<sup>®</sup> S Oral Drops / Orale Druppels

**Read all of this leaflet carefully because it contains important information for you**

Traumeel<sup>®</sup> S is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use Traumeel<sup>®</sup> S carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Traumeel<sup>®</sup> 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.

## 1. What Traumeel<sup>®</sup> S contains

Each 100 ml of solution contain:

The active substances are: Arnica montana D2 5 ml, Calendula officinalis D2 5 ml, Hamamelis virginiana D2 5 ml, Achillea millefolium D3 5 ml, Atropa belladonna D4 25 ml, Aconitum napellus D3 10 ml, Mercurius solubilis Hahnemanni D8 10 ml, Hepar sulfuris D8 10 ml, Chamomilla recutita D3 8 ml, Symphytum officinale D8 8 ml, Bellis perennis D2 2 ml, Echinacea angustifolia D2 2 ml, Echinacea purpurea D2 2 ml, Hypericum perforatum D2 1 ml. The other ingredient is: Purified water. Contains 35 % v/v ethyl alcohol.

## 2. What Traumeel<sup>®</sup> S is used for

Pharmacological classification: D. 33.2. Homeopathy.

Discipline of the medicine: Homeopathy

Traumeel<sup>®</sup> S is indicated in injuries such as sprains, dislocations, contusions, effusions of blood and effusions into a joint, fractures; post-operative and post-traumatic oedema and swelling of the soft tissues; inflammatory processes and degenerative processes associated with inflammation on the various organs and tissues, including, in particular, on the support and mobility apparatus (tendovaginitis, styloiditis, epicondylitis, bursitis, scapulo-humeral periarthritis); arthrosis of the hip, knee and small joints; commotio cerebri acuta.

## 3. Before you take Traumeel<sup>®</sup> S

**Do not take Traumeel<sup>®</sup> S:**

- if you are hypersensitive (allergic) to the active substance or any of the other ingredients of Traumeel<sup>®</sup> S, to Arnica, Chamomilla, Achillea millefolium or to other plants of the daisy (composite) family.
- As a matter of principle, Echinacea should not be used in progressive, systemic diseases such as tuberculosis, leukaemia or leukaemia-like diseases, inflammatory diseases of the connective tissue (collagen disease), autoimmune diseases, multiple sclerosis, AIDS, HIV infections or other chronic viral diseases.

**Take special care with Traumeel<sup>®</sup> S:**

Traumeel<sup>®</sup> S should not be administered for pain for more than 10 days for adults or 5 days for children unless directed by a medical practitioner. If pain persists or worsens, if new symptoms occur, or if redness or swelling is present, you should consult a medical practitioner because these could be signs of a serious condition. Traumeel<sup>®</sup> S should not be administered to children for the pain of arthritis unless directed by a medical practitioner.

**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<sup>®</sup> S:**

Contains 35 % v/v ethyl alcohol.

**Paediatric Use:**

Due to its alcohol content (35 vol.-% v/v ethyl alcohol), a medical practitioner should be consulted before using Traumeel<sup>®</sup> S in children below 12 years.

**Taking other medicines with Traumeel<sup>®</sup> S:**

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

## 4. How to take Traumeel<sup>®</sup> S

Do not share medicines prescribed for you with any other person. Always take Traumeel<sup>®</sup> 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 above 11 years: 10 drops orally 3 times daily; for swelling of the soft tissues 30 drops 3 times daily. Hold in mouth 10-15 seconds before swallowing.

Infants and Children to 11 years: Due to its alcohol content (35 vol.-% v/v ethyl alcohol), a medical practitioner should be consulted before using Traumeel<sup>®</sup> S for children below 12 years.

For best results, Traumeel<sup>®</sup> S should be administered on an empty stomach. Traumeel<sup>®</sup> S may be added to clear, non-sparkling water prior to administration.

**If you take more Traumeel<sup>®</sup> S than you should:**

Due to the low concentration of active ingredients in homeopathic preparations such as Traumeel<sup>®</sup> S, adverse reactions following over dosage are extremely unlikely. However, care must be taken not to exceed the recommended dosage.

In the event of over dosage, 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<sup>®</sup> S:**

Do not take a double dose to make up for forgotten individual doses.

## 5. Possible side effects

Traumeel<sup>®</sup> S can have side effects.

Hypersalivation may occur after administration, in which case the product should be discontinued. Hypersensitivity reactions or allergic skin reactions (redness, swelling and pruritus) can occur in individual cases in people with known hypersensitivity to plants of the composite family (e.g. Arnica, Chamomilla, Achillea millefolium), in which case the product should be discontinued, too. Skin rash and itching (pruritus), and in rare cases facial swelling, shortness of breath (dyspnoea), dizziness and a fall in blood pressure, have been observed after treatment with products containing Echinacea extracts.

Not all side effects reported for Traumeel<sup>®</sup> S are included in this leaflet. Should your general health worsen 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.

## 6. Storing and disposing of Traumeel<sup>®</sup> S

Keep all medicines out of the reach and sight of children.

- Store in a cool (below 25 °C) place.

## 7. Presentation of Traumeel<sup>®</sup> S

Bottles of 30 ml and 100 ml.

## 8. Identification of Traumeel<sup>®</sup> S

Light yellow solution with a light odour of alcohol.

## 9. Registration number / Reference number

U 5540 (Act 101/1965)

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

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

## 11. Date of publication

July 2018

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

Pasiënt Inligtingstuk

081281/5001 ZA

#### Skeduleringstatus

Skedule 0

Handelsnaam, sterkte en farmaseutiese vorm

**Lees die hele inligtingstuk versigtig aangesien dit belangrike inligting bevat**

Traumeel<sup>®</sup> S is sonder 'n doktersvoorskrif beskikbaar om 'n ligte siektetoestand te behandel. Nogtans moet u Traumeel<sup>®</sup> S versigtig gebruik word om die beste resultate te verkry.

- Hou hierdie inligtingstuk. U mag dit weer moet lees.
- Moenie Traumeel<sup>®</sup> 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. Wat Traumeel<sup>®</sup> S bevat

Elke 100 ml oplossing bevat:

Die aktiewe bestanddele is: Arnica montana D2 5 ml, Calendula officinalis D2 5 ml, Hamamelis virginiana D2 5 ml, Achillea millefolium D3 5 ml, Atropa belladonna D4 25 ml, Aconitum napellus D3 10 ml, Mercurius solubilis Hahnemanni D8 10 ml, Hepar sulfuris D8 10 ml, Chamomilla recutita D3 8 ml, Symphytum officinale D8 8 ml, Bellis perennis D2 2 ml, Echinacea angustifolia D2 2 ml, Echinacea purpurea D2 2 ml, Hypericum perforatum D2 1 ml. Die ander bestanddele is: Gesuiwerde water. Bevat 35 % v/v etielalkohol.

## 2. Waarvoor Traumeel<sup>®</sup> S gebruik word

Farmakologiese klassifikasie: D. 33.2. Homeopatie.

Dissipline van die medisyne: Homeopatie

Traumeel<sup>®</sup> S word aangedui in beserings soos verstuitings, ontwrigtings, kneusings, effusies van bloed en effusies in 'n gewrig, frakture; post-operatiewe en post-traumatisiese edeem en swelling van die sagteweefsel; inflammatoriese en degeneratiewe prosesse geassosieer met inflammasie van verskeie organe en weefsels, insluitend, in die besonder, op die ondersteunings- en mobiliteitsapparaat (tendovaginitis, stiloïditis, epikondilitis, bursitis, skapulo-humerale periartritis); artrose van die heup, knie en klein gewrigte; commotio cerebri acuta.

## 3. Voordat u Traumeel<sup>®</sup> S neem

**Moenie Traumeel<sup>®</sup> S neem:**

- indien u hipersensitief (allergies) is vir die aktiewe bestanddele of enige van die ander bestanddele van Traumeel<sup>®</sup> S, vir Arnica, Kamomilla, Achillea millefolium of vir ander plante van die daisy (composite) familie.
- As 'n beginsel moet Echinacea nie gebruik word in progressiewe, sistemiese siektes soos tuberkulose, leukemie of leukemiesoortige siektes, inflammatoriese siektes van die bindweefsel (kollageen-siekte), outo-immuunsiektes, veelvoudige sklerose, VIGS, MIV infeksies of ander chroniese virale siektes.

**Neem spesiale voorsorg met Traumeel<sup>®</sup> S:**

Traumeel<sup>®</sup> S moet nie vir langer as 10 dae in volwassenes en 5 dae in kinders vir pyn toegedien word tensy anders deur 'n mediese praktisyen voorgeskryf nie. Indien pyn voortduur of vererger, indien nuwe simptome verskyn of as rooiheid of swelling aanwesig is, moet u 'n mediese praktisyen raadpleeg aangesien dit tekens van 'n ernstige toestand kan wees. Traumeel<sup>®</sup> S moet nie aan kinders vir artritis pyn toegedien word tensy deur 'n mediese praktisyen voorgeskryf nie.

**Swangerskap en Borsvoeding**

Indien u swanger is of u baba borsvoed terwyl u hierdie medisyne neem moet u geneesheer, apteker of ander professionele gesondheidswerker vir advies geraadpleeg word.

**Belangrike inligting omtrent sekere van die bestanddele van Traumeel<sup>®</sup> S:**

Bevat 35 % v/v etielalkohol.

**Pediatrisiese Gebruik:**

As gevolg van die alkoholinhoud (35 vol.-% v/v etielalkohol), moet 'n mediese praktisyen geraadpleeg word alvorens Traumeel<sup>®</sup> S aan kinders onder 12 jaar toegedien word.

**Die neem van ander medisyne met Traumeel<sup>®</sup> S:**

Indien u op 'n gereelde basis ander medisyne neem, insluitend komplementêre of tradisionele medisyne, mag die gebruik van Traumeel<sup>®</sup> S saam met hierdie medisyne tot ongewenste interaksies lei. Raadpleeg asseblief u geneesheer, apteker of ander professionele gesondheidswerker vir advies.

## 4. Hoe om Traumeel<sup>®</sup> S te neem

Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.

Neem Traumeel<sup>®</sup> S altyd presies soos wat u geneesheer dit voorgeskryf het. Kontroleer met u geneesheer of apteker indien u onseker is.

Die gewone dosering is:

Volwassenes en kinders bo 11 jaar: 10 druppels oraal 3 maal per dag; vir swelling van die sagteweefsel, 30 druppels 3 maal per dag. Hou in die mond vir 10-15 sekondes voordat dit gesluk word.

Babas en kinders tot 11 jaar: As gevolg van die alkoholinhoud (35 vol.-% v/v etielalkohol), moet 'n mediese praktisyen geraadpleeg word voordat Traumeel<sup>®</sup> S aan kinders onder 12 jaar toegedien word.

Vir die beste resultate moet Traumeel<sup>®</sup> S op 'n leë maag toegedien word.

Traumeel<sup>®</sup> S mag voor toediening by kleurlose, nie-vonkel water gevoeg word.

**Indien u meer Traumeel<sup>®</sup> S neem as wat u moet:**

As gevolg van die lae konsentrasies van aktiewe bestanddele in homeopatisiese preparate soos Traumeel<sup>®</sup> S, is ongunstige reaksies na oordosering uiters onwaarskynlik. Nogtans moet sorg geneem word om nie die aanbevole dosering te oorskrei nie.

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<sup>®</sup> S te neem:**

Moenie 'n dubbeldosis neem om op te maak vir vergete individuele dosisse nie.

## 5. Moontlike nuwe-effekte

Traumeel<sup>®</sup> S kan nuwe-effekte hê.

Verhoogde speekselafskieding mag na toediening voorkom, in welke geval gebruik van die produk gestaak moet word. Hipersensitiwiteitsreaksies of allergiese velreaksies (rooiheid, swelling en pruritis) mag in individuele gevalle voorkom by persone met 'n bekende hipersensitiwiteit vir plante van die composiet familie (b.v. Arnica, Kamomille, Achillea millefolium), in welke geval gebruik van die produk ook gestaak moet word. Veluitslag en jeuk (pruritis), en in seldsame gevalle gesigswelling, kortasem (dispnee), duiseligheid en 'n afname in bloeddruk is waargeneem na die behandeling met produkte wat Echinacea ekstrakte bevat.

Nie alle nuwe-effekte wat vir Traumeel<sup>®</sup> S gerapporteer is word in hierdie inligtingstuk vermeld nie. Indien u algemene gesondheid vererger terwyl u hierdie medisyne neem, raadpleeg asseblief u geneesheer, apteker of ander professionele gesondheidswerker vir advies.

Indien u enige nuwe-effekte bemerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief u geneesheer of apteker in kennis.

## 6. Opberging van en beskikking oor Traumeel<sup>®</sup> S

Hou alle medisyne buite die bereik en sig van kinders.

- Hou in 'n koel (onder 25 °C) plek.

## 7. Aanbieding van Traumeel<sup>®</sup> S

Bottels van 30 ml en 100 ml.

## 8. Identifikasie van Traumeel<sup>®</sup> S

Liggeel oplossing met 'n ligte alkoholgeur.

## 9. Registrasienuommer / Verwysingsnommer

U 5540 (Wet 101/1965)

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

ModHomCo (Edms) Bpk  
Amsterdamstraat 96, Clubview, 0157 Centurion

## 11. Datum van publikasie

Julie 2018

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