

Patient information leaflet

#### Scheduling status

Schedule 0

#### Proprietary name, strength and pharmaceutical form

# Traumeel<sup>®</sup> S Ointment / Salf

## 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

For each 100 g of ointment:

The active substances are: Arnica montana D3 1.5 g; Calendula officinalis Ø 0.45 g; Hamamelis virginiana Ø 0.45 g; Echinacea angustifolia Ø 0.15 g; Echinacea purpurea Ø 0.15 g; Chamomilla recutita Ø 0.15 g; Symphytum officinale D4 0.1 g; Bellis perennis Ø 0.1 g; Hypericum perforatum D6 0.09 g; Achillea millefolium Ø 0.09 g; Aconitum napellus D1 0.05 g; Atropa belladonna D1 0.05 g; Mercurius solubilis Hahnemanni D6 0.04 g; Hepar sulfuris D6 0.025 g.

The other ingredients are: Cetostearyl alcohol (type A) emulsifying; Ethanol (96 per cent); Paraffin, liquid; Paraffin, white soft; Water, purified. Preservative: 13.8 % 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 of all kinds (sports, accidents) such as sprains, dislocations, contusions, effusions of blood and effusions into a joint, fractures, etc; inflammatory processes and degenerative processes associated with inflammation on the various organs and tissues (e.g. periodontitis, suppuration of the gingival pockets, periodontosis), including, in particular, on the support and mobility apparatus (tendovaginitis, bursitis, scapulohumeral periarthritis); arthrosis of the hip, knee and small joints.

## 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
  - the plants of the daisy (compositae) family (e.g. Arnica, Chamomilla, Achillea millefolium).

### Pregnancy and breastfeeding

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

### Important information about some of the ingredients of Traumeel<sup>®</sup> S:

Preservative: 13.8 % v/v ethyl alcohol.

### 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.

Always tell your healthcare professional if you are taking any other medicine.

## 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, children and infants: apply ointment generously to the affected area 2 to 3 times daily.

Traumeel<sup>®</sup> S should be rubbed gently into the skin. Traumeel<sup>®</sup> S may be applied using mild compression bandaging and/or occlusive bandaging. Sufficient ointment should be applied to cover the affected area, but should not be applied over large areas. Avoid contact with eyes, mucosae, open wounds or broken skin.

### 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.

Hypersensitivity reactions may occur in individual cases. Local allergic reactions (cutaneous inflammation, redness, swelling and pruritus) have been reported. In this case the product should be discontinued.

Not all side effects reported for Traumeel<sup>®</sup> 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.

## 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.
- Replace cap tightly.

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

Tubes containing 25 g, 50 g and 100 g of ointment.

Sachets containing 4 g of ointment.

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

White ointment.

## 9. Registration number/reference number

U 5684 (Act 101/1965)

## 10. Name and address of registration holder

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

081280/5001

ZA

#### Skeduleringstatus

Skedule 0

#### Handelsnaam, sterkte en farmaseutiese vorm

## Lees die hele inligtingstuk noukeurig aangesien dit belangrike inligting bevat.

Traumeel<sup>®</sup> S is sonder 'n doktersvoorskrif beskikbaar om 'n ligte siek-tetoestand te behandel.

Nogtans sal u Traumeel<sup>®</sup> S versigtig moet gebruik om die beste resultate te kry.

- Hou hierdie inligtingstuk. Dit mag dalk nodig wees om dit weer te lees.
- Moenie Traumeel<sup>®</sup> S met enige ander persoon deel nie.
- Vra u apteker indien meer inligting of advies benodig word.
- Raadpleeg 'n geneesheer indien u simptome vererger of nie verbeter verkry.

## 1. Wat Traumeel<sup>®</sup> S bevat

Vir elke 100 g salf:

Is die aktiewe bestanddele is: Arnica montana D3 1.5 g; Calendula officinalis Ø 0.45 g; Hamamelis virginiana Ø 0.45 g; Echinacea angustifolia Ø 0.15 g; Echinacea purpurea Ø 0.15 g; Chamomilla recutita Ø 0.15 g; Symphytum officinale D4 0.1 g; Bellis perennis Ø 0.1 g; Hypericum perforatum D6 0.09 g; Achillea millefolium Ø 0.09 g; Aconitum napellus D1 0.05 g; Atropa belladonna D1 0.05 g; Mercurius solubilis Hahnemanni D6 0.04 g; Hepar sulfuris D6 0.025 g.

Die ander bestanddele is: Emulsifiserende Cetostearialkohol (tipe A); Etanol (96 persent); Vloeibare Paraffien; Sagte Wit Paraffien; Gesuiwerde Water.

Preserveermiddel: 13.8 % 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 vir alle tipes beserings (sport/ongelukke) soos verstuiwings, ontwrigtings, kneusings, effussies van bloed en effusies in 'n gewrig, frakture ens.: inflammatoriese prosesse en degeneratiewe prosesse wat met inflammasie van die verskillende organe en weefsels geassosieer word (b.v. periodontitis, suppurasie van die gingivale sakke, periodontose), insluitend, in die besonder, op die ondersteunende en mobiliteitsapparaat (tendovaginitis, bursitis, skapulohumerale periartritis); artrose van die heup, knie en ander klein gewrigte.

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

### Moenie Traumeel<sup>®</sup> S gebruik:

- indien u sensitief (allergies) is vir
  - die aktiewe bestanddele of enige van die ander bestanddele van Traumeel<sup>®</sup> S
  - die plante van die daisy (madeliefie)(compositae) familie (b.v. Arnica, Kamomille, Achillea millefolium).

### Swangerskap en borsvoeding

Indien u swanger is of u baba borsvoed, raadpleeg u geneesheer, apteker of ander gesondheidsorgwerker vir advies voordat u hierdie medisyne neem.

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

Preserveermiddel: 13.8 % v/v etielalkohol.

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

Indien u enige ander medisyne op 'n gereelde grondslag neem, ingesluit komplementêre of tradisionele medisyne, mag die gebruik van Traumeel<sup>®</sup> S ongewenste interaksies tot gevolg hê. Stel altyd u professionele gesondheidsorgwerker in kennis indien u enige ander medisyne neem.

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

Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie. Gebruik Traumeel<sup>®</sup> S altyd presies soos dit deur u geneesheer voorgeskryf is. Kontroleer met u geneesheer of apteker indien u onseker is.

Die gewone dosis is: Volwassenes, kinders en babas: Wend die salf 2 tot 3 maal per dag middelik aan die geëffekteerde area aan.

Traumeel<sup>®</sup> S moet liggies in die vel ingevryf word. Traumeel<sup>®</sup> S mag aangewend word deur gebruik te maak van ligte kompressieverbande en/of okklusiewe verbande. Genoegsame salf moet aangewend word om die geëffekteerde area te bedek maar moet nie oor groot areas aangewend word nie. Vermoë kontak met die oë, slymliese, oop wonde of stukkende vel.

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

As gevolg van die lae konsentrasie van die aktiewe bestanddele in homeopatiëse preparate soos Traumeel<sup>®</sup> S is ongunstige reaksies na oordosering uiters onwaarskynlik. Sorg moet egter geneem word om nie die aanbevole dosis te oorskry nie.

In die geval van oordosering moet u geneesheer of apteker geraadpleeg word. Indien nie een van hulle beskikbaar is nie moet u die naaste hospital of gifbeheersentrum kontak.

### Indien u vergeet om Traumeel<sup>®</sup> S te gebruik:

Moenie 'n dubbeldosering gebruik om voorsiening te maak vir die individuele dosis wat u nie gebruik het nie.

## 5. Moontlike nuwe-effekte

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

Hypersensitiwiteitsreaksies mag in individuele gevalle voorkom. Plaaslike allergiese reaksies (velinflammasie, rooiheid, swelling en pruritis) is gerapporteer. In hierdie geval moet gebruik van die produk onmiddellik gestaak word.

Nie alle nuwe-effekte wat vir Traumeel<sup>®</sup> S gerapporteer is word in hierdie inligtingstuk ingesluit nie.

Indien u algemene gesondheid versleg of indien u enige nuwe-effekte ondervind terwyl u hierdie medisyne gebruik, raadpleeg u geneesheer, apteker of ander professionele gesondheidswerker vir advies.

Indien u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, raadpleeg u geneesheer of apteker.

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

Hou alle medisyne buite die bereik en sig van kinders.

- Bere in 'n koel (onder 25 °C) plek.
- Plaas proppe styf terug.

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

Buise bevattende 25 g, 50 g and 100 g salf.

Sakkies bevattende 4 g salf.

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

Wit salf.

## 9. Registrasienommer/Verwysingsnommer

U 5684 (Wet 101/1965)

## 10. Naam en adres van die registrasiehouer

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.

health|nature|future



ModHomCo

Distribution Partner

-Heel