

Patient information leaflet

Scheduling status

Schedule 0

Proprietary name, strength and pharmaceutical form



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.

1. What Traumeel® S contains

10 g gel contains:

The active substances are: Arnica montana D3 0,15 g, Calendula officinalis D0 0,045 g, Hamamelis virginiana D0 0,045 g, Echinacea angustifolia D0 0,015 g, Echinacea purpurea D0 0,015 g, Chamomilla recutita D0 0,015 g, Symphytum officinale D4 0,01 g, Bellis perennis D0 0,01 g, Hypericum perforatum D6 0,009 g, Achillea millefolium D0 0,009 g, Aconitum napellus D1 0,005 g, Atropa belladonna D1 0,005 g, Mercurius solubilis Hahnemanni D6 0,004 g, Hepar sulfuris D6 0,0025 g.

The other ingredients are: Purified water, Ethanol (96 per cent), Carbomers, Sodium hydroxide solution 18 % (m/m). Preservative: 17.9 % v/v ethyl alcohol.

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.

3. Before you use Traumeel® S

Do not use Traumeel® S:

- if you are hypersensitive (allergic) 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).

Pregnancy and breastfeeding

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

Important information about some of the ingredients of Traumeel® S:

Preservative: 17.9 % m/m ethyl alcohol.

Using other medicines with Traumeel® S:

If you are using 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.

4. How to use Traumeel® S

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

For external use only.

Avoid contact with eyes, mucosae, open wounds or broken skin.

The usual dose is:
Apply to the affected parts 1-2 times daily, or more often if necessary.

A dressing may be applied.
Replace cap tightly.
Do not use on open wounds.

If you use 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 use Traumeel® S:

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

5. Possible side effects

Traumeel® S can have side effects.
In isolated cases, hypersensitivity reactions may occur.
Local allergic reactions (skin inflammation) have been reported.

Not all side effects reported for Traumeel® 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® S

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

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

7. Presentation of Traumeel® S

Tubes containing 50 g of gel.

8. Identification of Traumeel® S

Clear gel.

9. Registration number / Reference number

To be allocated by the SAHPRA.

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

January 2024

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

Pasiënt-inligtingstuk

047487/5010/ZA

Skeduleringstatus

Skedule 0

Handelsnaam, sterkte en farmaseutiese vorm

Lees die hele voubiljet aangesien dit belangrike inligting bevat.

Traumeel® S is sonder 'n voorskrif beskikbaar om 'n ligte siekte te behandel. Nogtans moet u Traumeel® S versigtig gebruik 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. Wat Traumeel® S bevat

10 g gel bevat:

Die aktiewe bestanddele is: Arnica montana D3 0,15 g, Calendula officinalis D0 0,045 g, Hamamelis virginiana D0 0,045 g, Echinacea angustifolia D0 0,015 g, Echinacea purpurea D0 0,015 g, Chamomilla recutita D0 0,015 g, Symphytum officinale D4 0,01 g, Bellis perennis D0 0,01 g, Hypericum perforatum D6 0,009 g, Achillea millefolium D0 0,009 g, Aconitum napellus D1 0,005 g, Atropa belladonna D1 0,005 g, Mercurius solubilis Hahnemanni D6 0,004 g, Hepar sulfuris D6 0,0025 g.

Die ander bestanddele is: Gesuiwerde water, Etanol (96 persent), Karbomere, Natriumhidroksied oplossing 18 % (m/m). Preserweermiddel: 17,9 % v/v etielalkohol.

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. Voordat u Traumeel® S gebruik

Moenie Traumeel® S gebruik:

- indien u hipersensitief (allergies) is vir
 - een of meer van die bestanddele, insluitend plante van die madeliefiefamilie (Asteraceae) soos Arnica montana (arnica), Calendula officinalis (goudsblom), Chamomilla recutita (kamille), Echinacea (keëlblom), Achillea millefolium (duisendblad), Bellis perennis (madeliefie).

Swangerskap en borsvoeding

Indien u swanger is of u baba borsvoed terwyl u hierdie medisyne gebruik, raadpleeg asseblief u geneesheer, apteker of ander professionele gesondheidswerker vir advies.

Belangrike inligting omtrent sommige van die bestanddele van Traumeel® S:

Preserweermiddel: 17,9 % m/m etielalkohol.

Die gebruik van ander medisyne saam met Traumeel® S:

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

4. Hoe om Traumeel® S te gebruik

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

Gebruik Traumeel® S altyd presies soos wat dit vir u voorgeskryf is. U moet met u geneesheer of apteker kontroleer indien u onseker is.

Slegs vir eksterne gebruik.

Vermý kontak met oë, slymvliese, oop wonde of stukkende vel.

Die gewone dosis is:
Wend aan die geaffekteerde dele 1-2 maal per dag, of meer dikwels indien nodig.

'n Verband mag gebruik word.
Plaas proppie styf terug.
Moenie op oop wonde gebruik nie.

Indien u meer Traumeel® S gebruik as wat u moet:

In die geval van 'n 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 gebruik:

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

5. Moontlike nuwe-effekte

Traumeel® S kan nuwe-effekte hê.
In geïsoleerde gevalle mag hipersensitiwiteitsreaksies voorkom.
Plaaslike allergiese reaksies (velinflammasie) is gerapporteer.

Nie alle nuwe-effekte wat vir Traumeel® S gerapporteer is word in hierdie inligtingstuk ingesluit nie. Sou u algemene gesondheid vererger terwyl u hierdie medisyne gebruik, raadpleeg asseblief u geneesheer, apteker of ander professionele gesondheidswerker vir advies.

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

6. Opberging van en beskikking oor Traumeel® S

Hou alle medisyne buite die bereik en sig van kinders.

- Hou in 'n koel (onder 25 °C) plek.

7. Aanbieding van Traumeel® S

Buise bevattende 50 g gel.

8. Identifikasie van Traumeel® S

Helder gel.

9. Registrasienommer / Verwysingsnommer

Om deur die SAHPRA toegeken te word.

10. Naam en besigheidsadres van die houer van die registrasiesertifikaat

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

11. Datum van publikasie

Januarie 2024

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

-Heel





1. Scheduling status

Schedule 0

2. Proprietary name and dosage form

Traumeel® S Gel

3. Composition

10 g gel contains: Arnica montana D3 0,15 g, Calendula officinalis D0 0,045 g, Hamamelis virginiana D0 0,045 g, Echinacea angustifolia D0 0,015 g, Echinacea purpurea D0 0,015 g, Chamomilla recutita D0 0,015 g, Symphytum officinale D4 0,01 g, Bellis perennis D0 0,01 g, Hypericum perforatum D6 0,009 g, Achillea millefolium D0 0,009 g, Aconitum napellus D1 0,005 g, Atropa belladonna D1 0,005 g, Mercurius solubilis Hahnemanni D6 0,004 g, Hepar sulfuris D6 0,0025 g.

Excipients: Purified water, Ethanol (96 per cent), Carbomers, Sodium hydroxide solution 18 % (m/m).

Preservative: 17.9 % m/m ethyl alcohol.

4. Pharmacological classification

D. 33.2. Homeopathy.

5. Pharmacological action

Action based on homeopathic principles.

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.

7. Contraindications

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).

8. Warnings

None.

9. Interactions

No interactions have been reported, and none are expected due to the homeopathic dilutions and external use.

10. Pregnancy and lactation

Safety and/or efficacy has not been established.

11. Dosage and directions for use

For external use only.

Avoid contact with eyes, mucosae, open wounds or broken skin.

Apply to the affected parts 1-2 times daily, or more often if necessary.

Traumeel® S may be applied using mild compression bandaging and/or occlusive bandaging.

Replace cap tightly.

Do not use on open wounds.

12. Side effects and special precautions

12.1 Side effects

In isolated cases, hypersensitivity reactions may occur. Local allergic reactions (skin inflammation) have been reported.

12.2 Special precautions

Preservative: 17.9 % m/m ethyl alcohol.

12.3 Effects on ability to drive and use machines

13. Known symptoms of overdose and particulars of its treatment

None known.

14. Identification

Clear gel.

15. Presentation

Tubes containing 50 g of gel.

16. Storage instructions

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

17. Registration number

To be allocated by the SAHPRA.

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.

19. Date of publication of the professional information

January 2024

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

1. Skeduleringstatus

Skedule 0

2. Handelsnaam en doseervorm

Traumeel® S Gel

3. Samestelling

10 g gel bevat: Arnica montana D3 0,15 g, Calendula officinalis D0 0,045 g, Hamamelis virginiana D0 0,045 g, Echinacea angustifolia D0 0,015 g, Echinacea purpurea D0 0,015 g, Chamomilla recutita D0 0,015 g, Symphytum officinale D4 0,01 g, Bellis perennis D0 0,01 g, Hypericum perforatum D6 0,009 g, Achillea millefolium D0 0,009 g, Aconitum napellus D1 0,005 g, Atropa belladonna D1 0,005 g, Mercurius solubilis Hahnemanni D6 0,004 g, Hepar sulfuris D6 0,0025 g.

Bymiddels: Gesuiwerde water, Etanol (96 persent), Karbomere, Natriumhidroksied oplossing 18 % (m/m).

Preserveermiddel: 17,9 % m/m etielalkohol.

4. Farmakologiese klassifikasie

D. 33.2. Homeopatie.

5. Farmakologiese werking

Werking gebaseer op homeopatiese beginsels.

6. Indikasies

Traumeel® S is voorberei volgens homeopatiese beginsels en word aangedui vir die behandeling van alle tipes verstuiings, 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. Kontra-indikasies

Hipersensitiwiteit vir een of meer van die bestanddele, insluitend plante van die madeliefiefamilie (Asteraceae) soos Arnica montana (arnica), Calendula officinalis (goudsblom), Chamomilla recutita (kamille), Echinacea (keëlblom), Achillea millefolium (duisendblad), Bellis perennis (madeliefie).

8. Waarskuwings

Geen.

9. Interaksies

Geen interaksies is aangemeld nie en as gevolg van die homeopatiese verdunnings en uitwendige gebruik, word geen interaksies verwag nie.

10. Swangerskap en borsvoeding

Veiligheid en/of doeltreffendheid is nie vasgestel nie.

11. Dosering en gebruiksaanwysings

Slegs vir eksterne gebruik.

Vermý kontak met oë, slymvliese, oop wonde of stukkende vel.

Wend aan die geaffecteerde dele 1-2 maal per dag, of meer dikwels indien nodig.

Traumeel® S kan met 'n ligte kompressieverband en/of okklusiewe verbande toegedien word.

Plaas proppie styf terug.

Moenie op oop wonde gebruik nie.

12. Nuwe-effekte en spesiale voorsorgmaatreëls

12.1 Nuwe-effekte

In geïsoleerde gevalle mag hipersensitiwiteitsreaksies voorkom.

Plaaslike allergiese reaksies (velinflammasie) is gerapporteer.

12.2 Spesiale voorsorgmaatreëls

Preserveermiddel: 17,9 % m/m etielalkohol.

12.3 Effekte op die vermoë om motorvoertuie te bestuur en masjinerie te gebruik

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

Geen bekend nie.

14. Identifikasie

Helder gel.

15. Aanbieding

Buise bevattende 50 g gel.

16. Opbergingsinstruksies

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

17. Registrasienommer

Om deur die SAHPRA toegeken te word.

18. Naam en besigheidsadres van die houer van die registrasiesertifikaat

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

19. Datum van publikasie van hierdie professionele inligting

Januarie 2024

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