Patient information leaflet

Scheduling status
Schedule 0

Proprietary name, strength and pharmaceutical form

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.

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.

2. What Traumeel® S is used for

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

This medicine is prepared in accordance with homeopathic principles and is proposed for use 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, scapulohumeral periarthritis); arthrosis of the hip, knee and small joints; commotio cerebri acuta.

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 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.

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.

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.

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.

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.

7. Presentation of Traumeel® S

Containers of 50 and 250 tablets.

8. Identification of Traumeel® S

White to light yellow tablets, sometimes small orange dots.

9. Registration number / Reference number

U 5514 (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

081278/5001 ZA

Skeduleringstatus
Skedule 0

Handelsnaam, sterkte en farmaseutiese vorm

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 u 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. 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. Waarvoor Traumeel® S gebruik word

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

Hierdie medisyne is in ooreenstemming met homeopatiese beginsels voorberei en word aangedui vir alle tipes beserings (sport/ongelukke) soos verstuitings, 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, periodontosis), insluitend, in die besonder, op die ondersteunende en mobiliteitsapparatuur (tendovaginitis, bursitis, skapulohumerale periartritis); artrose van die heup, knie en ander klein gewrigte.

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, veelvoudige sklerose, VIGS, HIV infeksie en ander outo-immuunversteurings.

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 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 professionele 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 gereëlde 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. 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. 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. 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. Aanbieding van Traumeel® S

Houers van 50 en 250 tablette.

8. Identifikasie van Traumeel® S

Wit tot liggeel tablette, soms klein oranje spikkels.

9. Registrasienommer / Verwysingsnommer

U 5514 (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.