Patient information leaflet

Pasiënt-inligtingstuk

081281/5002/ZA

Scheduling status
Schedule 0

Skeduleringstatus
Skedule 0

Proprietary name, strength and pharmaceutical form

Handelsnaam, sterkte en farmaseutiese vorm

Traumeel® S Oral Drops / Orale Druppels

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

Each 1 ml of solution contain:
The active substances are: Arnica montana D2 0.06 ml, Calendula officinalis D2 0.05 ml, Hamamelis virginiana D2 0.05 ml, Achillea millefolium D3 0.05 ml, Atropa belladonna D4 0.25 ml, Aconitum napellus D3 0.1 ml, Mercurius solubilis Hahnemanni D8 0.1 ml, Hepar sulfuris D8 0.1 ml, Chamomilla recutita D3 0.08 ml, Symphytum officinale D8 0.08 ml, Bellis perennis D2 0.02 ml, Echinacea angustifolia D2 0.02 ml, Echinacea purpurea D2 0.02 ml, Hypericum perforatum D2 0.01 ml.
The other ingredient is: Purified water.
Contains 35 % 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 take Traumeel® S

Do not take Traumeel® S:
- if you are hypersensitive (allergic) to the active substance or any of the other ingredients of Traumeel® 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® S:
Traumeel® 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® 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® 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® S in children below 12 years.

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 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® S for children below 12 years.

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

If you take more Traumeel® S than you should:
Due to the low concentration of active ingredients in homeopathic preparations such as Traumeel® 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® S:
Do not take a double dose to make up for forgotten individual doses.

5. Possible side effects

Traumeel® 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® 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

Bottles of 30 ml and 100 ml.

8. Identification of Traumeel® 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

October 2023

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

Lees die hele inligtingstuk versigtig 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

Elke 1 ml oplossing bevat:
Die aktiewe bestanddele is: Arnica montana D2 0.06 ml, Calendula officinalis D2 0.05 ml, Hamamelis virginiana D2 0.05 ml, Achillea millefolium D3 0.05 ml, Atropa belladonna D4 0.25 ml, Aconitum napellus D3 0.1 ml, Mercurius solubilis Hahnemanni D8 0.1 ml, Hepar sulfuris D8 0.1 ml, Chamomilla recutita D3 0.08 ml, Symphytum officinale D8 0.08 ml, Bellis perennis D2 0.02 ml, Echinacea angustifolia D2 0.02 ml, Echinacea purpurea D2 0.02 ml, Hypericum perforatum D2 0.01 ml.
Die ander bestanddele is: Gesuiwerde water.
Bevat 35 % 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 neem

Moenie Traumeel® S neem:
- indien u hipersensitief (allergies) is vir die aktiewe bestanddele of enige van die ander bestanddele van Traumeel® S, vir Arnica, Kamomilla, Achillea millefolium of vir ander plante van die daisie (composite) familie.
- As 'n beginsel moet Echinacea nie gebruik word in progressiewe, sistemiese siektes soos tuberkulose, leukemie of leukemie-soortige siektes, inflammatoriese siektes van die bindweefsel (kollageensiekte), outo-immuunsiektes, veelvuldige sklerose, VIGS, MIV infeksies of ander chroniese virale siektes.

Neem spesiale voorsorg met Traumeel® S:
Traumeel® S moet nie vir langer as 10 dae in volwassenes en 5 dae in kinders vir pyn toegedien word tensy anders deur 'n mediese praktisyn voorgeskryf nie. Indien pyn voortduur of vererger, indien nuwe simptome verskyn of as rooiheid of swelling aanwesig is, moet u 'n mediese praktisyn raadpleeg aangesien dit tekens van 'n ernstige toestand kan wees. Traumeel® S moet nie aan kinders vir artritispyn toegedien word tensy deur 'n mediese praktisyn 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® S:
Bevat 35 % v/v etielalkohol.

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

Die neem van ander medisyne 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 tot ongewenste interaksies lei. 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 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 praktisyn geraadpleeg word voordat Traumeel® S aan kinders onder 12 jaar toegedien word.

Vir die beste resultate moet Traumeel® S op 'n leë maag toegedien word.
Traumeel® S mag voor toediening by kleurlose, nie-vonkel water gevoeg word.

Indien u meer Traumeel® S neem as wat u moet:
As gevolg van die lae konsentrasies van aktiewe bestanddele in homeopatiese preparate soos Traumeel® 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® 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 speekselafskeiding 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 compositae 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 newe-effekte wat vir Traumeel® 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 newe-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® S

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

7. Aanbieding van Traumeel® S

Bottels van 30 ml en 100 ml.

8. Identifikasie van Traumeel® S

Liggeel oplossing met 'n ligte alkoholgeur.

9. Registrasienommer / 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

Oktober 2023

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

-Heel

Professional Information

Professionele Inligting

Traumeel® S Oral Drops / Orale Druppels

1. Scheduling status

Schedule 0

2. Proprietary name and dosage form

Traumeel® S Oral Drops

3. Composition

Each 1 ml of solution contains as active ingredients: Arnica montana D2 0.06 ml, Calendula officinalis D2 0.05 ml, Hamamelis virginiana D2 0.05 ml, Achillea millefolium D3 0.05 ml, Atropa belladonna D4 0.25 ml, Aconitum napellus D3 0.1 ml, Mercurius solubilis Hahnemanni D8 0.1 ml, Hepar sulfuris D8 0.1 ml, Chamomilla recutita D3 0.08 ml, Symphytum officinale D8 0.08 ml, Bellis perennis D2 0.02 ml, Echinacea angustifolia D2 0.02 ml, Echinacea purpurea D2 0.02 ml, Hypericum perforatum D2 0.01 ml. Excipient: Purified water.
Contains 35 % v/v 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

Traumeel® S is contraindicated in patients with a known hypersensitivity to one of the active ingredients or excipients, 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.

8. Warnings

8.1 Warnings

Traumeel® 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, the patient should consult a medical practitioner because these could be signs of a serious condition. Traumeel® S should not be administered to children for the pain of arthritis unless directed by a medical practitioner.

8.2 Special precautions

Information for Patients:
No harmful or potentially hazardous side effects such as central nervous system depression are known. Traumeel® S is generally well-tolerated.

Carcinogenesis:
No studies have been performed to evaluate the carcinogenicity of Traumeel® S. In world-wide post-marketing surveillance studies no evidence of carcinogenicity has been found (2).

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

9. Interactions

Traumeel® S is not known to interact with other medications. Furthermore, the administration of an oral dosage form of Traumeel® S can be safely augmented by the application of a topical dosage form of Traumeel® S.
Drug/Laboratory Test Interactions: Traumeel® S is not known to interact with any laboratory tests.

10. Pregnancy and lactation

10.1 Pregnancy

In general, medications such as Traumeel® S that are classified as homeopathic are not known to cause direct or indirect harm to the fetus. However, animal reproduction studies have not been performed and there are no well-controlled studies in pregnant women. In cases of pregnancy or suspected pregnancy, a medical practitioner should be consulted before administering Traumeel® S.

10.2 Lactation

It is not known whether any of the ingredients in Traumeel® S are excreted in human milk. However, because many drugs are excreted in human milk, Traumeel® S should be administered with caution to nursing mothers.

11. Dosage and directions for use

The dosage schedules listed below can be used as a general guide for the administration of Traumeel® S. Traumeel® S shows individual differences in clinical response. Therefore, the dosage for each patient should be individualized according to the patient's response to therapy. The frequency of administration may be increased to 5 times daily for the treatment of acute symptoms in both children and adults, unless otherwise directed by a medical practitioner. The oral dosage forms of Traumeel® S should be administered at least 30 minutes after meals and when the oral cavity is free of food material. For best results, treatment with Traumeel® S should be initiated immediately following injury or at the first sign of symptoms. Traumeel® S may be administered until symptoms disappear. However, if symptoms persist or worsen, a medical practitioner should be consulted (see **8 Warnings**).

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® S for children below 12 years.

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

12. Side effects and special precautions

General:
Adverse effects with Traumeel® S are extremely rare. Traumeel® S exhibits no known adverse renal, hepatic, cardiovascular, gastrointestinal or central nervous system effects.

Adverse reactions:
In rare cases, patients with hypersensitivity to botanicals of the Compositae family may experience an allergic reaction after oral administration of Traumeel® S.
Traumeel® S ingredients of the Compositae family are:
Arnica montana (mountain arnica)
Calendula officinalis (calendula)
Achillea millefolium (milfoil)
Chamomilla recutita (chamomile)
Bellis perennis (daisy)
Echinacea angustifolia (narrow-leafed cone flower)
Echinacea purpurea (purple cone flower)

12.1 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.

12.2 Special precautions

12.3 Effects on ability to drive and use machines

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13. Known symptoms of overdosage and particulars of its treatment

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

14. Identification

Light yellow solution with a light odour of alcohol.

15. Presentation

Bottles of 30 ml and 100 ml.

16. Storage instructions

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

17. Registration number

U 5540 (Act 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.

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.

References:
(1) The Homeopathic Pharmacopoeia of the United States (HPUS), 8th edition, Falls Church, Virginia, 1979; and the Homeopathic Pharmacopoeia of the United States Revision Service (HPRS), 1988.
(2) Wagner, H: Untersuchungsbericht über immunologische und enzymchemische Wirknachweise durchgeführt mit dem Injektionspräparat Traumeel®. 1986, not published. Data on file, Heel GmbH, Baden-Baden, Germany.

1. Skeduleringstatus

Skedule 0

2. Handelsnaam en doseervorm

Traumeel® S Orale Druppels

3. Samestelling

Elke 1 ml oplossing bevat as aktiewe betsanddele: Arnica montana D2 0.06 ml, Calendula officinalis D2 0.05 ml, Hamamelis virginiana D2 0.05 ml, Achillea millefolium D3 0.05 ml, Atropa belladonna D4 0.25 ml, Aconitum napellus D3 0.1 ml, Mercurius solubilis Hahnemanni D8 0.1 ml, Hepar sulfuris D8 0.1 ml, Chamomilla recutita D3 0.08 ml, Symphytum officinale D8 0.08 ml, Bellis perennis D2 0.02 ml, Echinacea angustifolia D2 0.02 ml, Echinacea purpurea D2 0.02 ml, Hypericum perforatum D2 0.01 ml. Bymiddel: Gesuiwerde water.
Bevat 35 % v/v 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 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. Kontra-indikasies

Traumeel® S word teenaangedui in pasiënte met 'n bekende hipersensitiwiteit vir een van die aktiewe bestanddele of bymiddels, vir Arnica, Kamomilla, Achillea millefolium of vir ander plante van die daisie (composite) familie. As 'n beginsel moet Echinacea nie gebruik word in progressiewe, sistemiese siektes soos tuberkulose, leukemie of leukemie-soortige siektes, inflammatoriese siektes van die bindweefsel (kollageensiektes), outo-immuun siektes, veelvuldige sklerose, VIGS, MIV infeksies of ander chroniese virale siektes nie.

8. Waarskuwings

8.1 Waarskuwings

Traumeel® S moet nie vir meer as 10 dae aan volwassenes en 5 dae aan kinders toegedien word tensy deur 'n mediese praktisyn voorgeskryf nie. Indien pyn voortduur of vererger, indien nuwe simptome voorkom of indien rooiheid of swelling aanwesig is, moet die pasiënt 'n mediese praktisyn raadpleeg aangesien hierdie tekens van 'n ernstige aard kan wees. Traumeel® S moet nie vir artritispyn aan kinders toegedien word tensy deur 'n mediese praktisyn voorgeskryf nie.

8.2 Spesiale voorsorgmaatreëls

Inligting vir pasiënte:
Geen skadelike of potensiëel gevaarlike newe-effekte soos sentraal-senuweestelsel onderdrukking is bekend nie. Traumeel® S word in die algemeen goed verdra.

Karsinogenese:
Geen studies is uitgevoer om die karsinogenisiteit van Traumeel® S te evalueer nie. In wêreldwye na-bemarking toesigstudies was geen bewyse van karsinogenisiteit gevind nie (2).

Pediatriese gebruik:
As gevolg van die alkoholinhoud (35 vol.-% v/v etiel alkohol), moet 'n mediese praktisyn geraadpleeg te word voordat Traumeel® S in kinders onder 12 jaar gebruik word.

9. Interaksies

Traumeel® S is nie bekend vir interaksies met ander medisyne nie. Verder kan die toediening van Traumeel® S met veiligheid aangevul word deur aanwending van 'n plaaslike Traumeel® S doseervorm.
Geneesmiddel/Laboratorium Interaksies: Traumeel® S is nie bekend om met laboratorium toetse interaksies te hê nie.

10. Swangerskap en borsvoeding

10.1 Swangerskap

In die algemeen is medikasies soos Traumeel® S wat as homeopatiese geklassifiseer is, nie bekend om direkte of indirekte skade aan die fetus te veroorsaak nie. Dierereproduksiestudies is egter nie uitgevoer nie en daar is geen goed-gekontroleerde studies in swanger vroue uitgevoer nie. In gevalle van swangerskap of waar swangerskap vermoed word, moet 'n mediese praktisyn geraadpleeg word voor die toediening van Traumeel® S.

10.2 Borsvoeding

Dit is onbekend of enige van die bestanddele van Traumeel® S in menslike moedersmelk uitgeskei word. Aangesien baie geneesmiddels in menslike moedersmelk uitgeskei word, moet Traumeel® S met sorg aan borsvoedende vroue toegedien word.

11. Dosering en gebruiksaanwysings

Die doseringskedules soos hieronder gelys kan as 'n algemene riglyn vir die toediening van Traumeel® S gebruik word. Traumeel® S wys individuele verskille in kliniese respons. Daarom moet die dosering vir elke pasiënt geïndividualiseer word volgens die pasiënt se individuele respons op behandeling. Die frekwensie van toediening mag tot 5 maal per dag verhoog word vir die behandeling van akute simptome in beide volwassenes en kinders, tensy anders deur 'n mediese praktisyn voorgeskryf. Die orale doseervorms van Traumeel® S moet ten minste 30 minute na etes toegedien word wanneer die mondholte nie kosmateriaal bevat nie. Vir die beste resultate moet behandeling met Traumeel® S onmiddellik na besering of die eerste teken van simptome begin word. Traumeel® S mag toegedien word totdat die simptome verdwyn. Indien simptome egter voortduur of vererger, moet 'n mediese praktisyn geraadpleeg word (sien **8 Waarskuwings**).

Volwassenes en kinders bo 11 jaar: 10 druppels per mond 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 etiel alkohol), moet 'n mediese praktisyn geraadpleeg word vir kinders onder 12 jaar.

Vir die beste resultate moet Traumeel® S op 'n leë maag geneem word.
Traumeel® S mag voor toediening by helder nie-vonkel water gevoeg word.

12. Newe-effekte en spesiale voorsorgmaatreëls

Algemeen:
Ongunstige reaksies met Traumeel® S is uiters seldsaam. Traumeel® S vertoon geen bekende ongunstige renale, hepatiese, kardiovaskulêre, gastro-intestinale of sentraalsenuweestelsel effekte nie.

Ongunstige reaksies:
In seldsame gevalle mag pasiënte wat hipersensitief is vir plante van die Compositae familie 'n allergiese reaksie toon na die orale toediening van Traumeel® S.
Traumeel® S se bestanddele van die Compositae familie is:
Arnica montana (berg arnica)
Calendula officinalis (kalendula)
Achillea millefolium (millefolium)
Chamomilla recutita (kamomille)
Bellis perennis (daisie, madeliefie)
Echinacea angustifolia (smalblaar keëlblom)
Echinacea purpurea (pers keëlblom)

12.1 Newe-effekte

Verhoogde speekselafskeiding 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 compositae 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.

12.2 Spesiale voorsorgmaatreëls

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

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

As gevolg van die lae konsentrasie van aktiewe bestanddele in homeopatiese preparate soos Traumeel® S, is ongunstige reaksies as gevolg van oordosering uiters onwaarskynlik. Sorg moet nogtans geneem word om nie die aanbevole dosering te oorskrei nie.

14. Identifikasie

Liggeel oplossing met 'n ligte alkoholgeur.

15. Aanbieding

Bottels van 30 ml en 100 ml.

16. Opbergingsinstruksies

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

17. Registrasienommer

U 5540 (Wet 101/1965)

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

Oktober 2023

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

Verwysings:
(1) The Homeopathic Pharmacopoeia of the United States (HPUS), 8th edition, Falls Church, Virginia, 1979; and the Homeopathic Pharmacopoeia of the United States Revision Service (HPRS), 1988.
(2) Wagner, H: Untersuchungsbericht über immunologische und enzymchemische Wirknachweise durchgeführt mit dem Injektionspräparat Traumeel®. 1986, not published. Data on file, Heel GmbH, Baden-Baden, Germany.

-Heel