Patient information leaflet

Pasiënt-inligtingstuk 016336/5005/ZA

Scheduling status
Schedule 0

Skeduleringstatus
Skedule 0

Proprietary name, strength and pharmaceutical form

Handelsnaam, sterkte en farmaseutiese vorm

Spascupreel®

Tablets / Tablette

Read all of this leaflet carefully because it contains important information for you.
Spascupreel® is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use Spascupreel® carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share Spascupreel® 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.

Lees die hele inligtingstuk noukeurig aangesien dit belangrike inligting bevat.
Spascupreel® is sonder 'n doktersvoorskrif beskikbaar om 'n ligte siekte mee te behandel. Nogtans moet u Spascupreel® versigtig gebruik om die beste resultate te verkry.
- Hou hierdie inligtingstuk. U mag dit weer moet lees.
- Moenie Spascupreel® 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. What Spascupreel® contains

1 tablet cont.:
The active substances are: Citrullus colocynthis D4 30 mg, Ammonium bromatum D4 30 mg, Atropinum sulfuricum D6 30 mg, Veratrum album D6 30 mg, Magnesium phosphoricum D6 30 mg, Gelsemium sempervirens D6 30 mg, Passiflora incarnata D2 15 mg, Amanita muscaria D4 15 mg, Chamomilla recutita D3 15 mg, Cuprum sulfuricum D6 15 mg, Aconitum napellus D6 60 mg.
The other ingredient is: Magnesium stearate.
1 tablet contains approx. 300 mg lactose.

1. Wat Spascupreel® bevat

1 tablet bevat:
Die aktiewe bestanddele is: Citrullus colocynthis D4 30 mg, Ammonium bromatum D4 30 mg, Atropinum sulfuricum D6 30 mg, Veratrum album D6 30 mg, Magnesium phosphoricum D6 30 mg, Gelsemium sempervirens D6 30 mg, Passiflora incarnata D2 15 mg, Amanita muscaria D4 15 mg, Chamomilla recutita D3 15 mg, Cuprum sulfuricum D6 15 mg, Aconitum napellus D6 60 mg.
Die ander bestanddeel is: Magnesiumstearaat.
1 tablet bevat ong. 300 mg laktose.

2. What Spascupreel® 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 spasms in the organs of the smooth musculature (stomach, intestine, gall bladder, uterus, urinary tract); spasticity of the striated musculature (myogelosis, hardening of the muscles).

2. Waarvoor Spascupreel® gebruik word

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

Hierdie medisyne is in ooreenstemming met homeopatiese beginsels voorberei en word voorgestel vir gebruik in spasmas in die gladdespierorgane (maag, dermkanaal, galblaas, uterus, urienweg); spastisiteit van die gestreepte spiere (miogelose, verharding van die spiere).

3. Before you take Spascupreel®

Do not take Spascupreel®:
- if you are hypersensitive (allergic) to the active substances or any of the other ingredients of Spascupreel®.

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

3. Voordat u Spascupreel® neem

Moenie Spascupreel® neem:
- indien u hipersensitief (allergies) is vir die aktiewe bestanddele of enige van die ander bestanddele van Spascupreel® nie.

Swangerskap en borsvoeding:
Indien u swanger is of u baba borsvoed terwyl u hierdie medisyne neem, raadpleeg asseblief u geneesheer, apteker of ander professionele gesondheidswerker vir advies.

Belangrike inligting omtrent sommige van die bestanddele van Spascupreel®:
Hierdie preparaat bevat natuurlike laktose. Hoewel die hoeveelheid laktose aanwesig waarskynlik nie genoegsaam is om ongemak te veroorsaak nie, moet 'n professionele gesondheidswerker geraadpleeg word in gevalle van sterk laktose-intoleransie. 'n Tydelike verergering van die bestaande simptome is moontlik na die inname van 'n homeopatiese preparaat.

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

4. How to take Spascupreel®

Do not share medicines prescribed for you with any other person.
Always take Spascupreel® 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 12 years and older:
1 tablet 3x daily.
Children 6-11 years: 1 tablet 2x daily.
Children 2-5 years: 1 tablet 1-2x daily.
Infants up to 2 years: 1 tablet 1x daily.

Acute or initial dosage:
Adults and children 12 years and older: 1 tablet every ½ to 1 hour, up to 12x daily, and then continue with usual dosage.
Children 6-11 years: 1 tablet every 1 to 2 hours, up to 8x daily, and then continue with usual dosage.
Children 2-5 years: 1 tablet every 1 to 2 hours, up to 6x daily, and then continue with usual dosage.
Infants up to 2 years: 1 tablet every 1 to 2 hours, up to 4x daily, and then continue with usual dosage.

Method of administration:
The tablets should be allowed to dissolve slowly in the mouth.
For children and infants, it is recommended to crush the tablet and administer it dissolved in a little water.

It is recommended not to eat or drink 15 minutes before or after taking the medication.

If you take more Spascupreel® 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 Spascupreel®:
Do not take a double dose to make up for forgotten individual doses.

4. Hoe om Spascupreel® te neem

Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.
Neem Spascupreel® altyd presies soos wat dit vir u voorgeskryf is. U moet met u geneesheer of apteker kontroleer indien u onseker is.

Die gewone dosis is:
Volwassenes en kinders 12 jaar en ouer:
1 tablet 3x daagliks.
Kinders 6-11 jaar: 1 tablet 2x daagliks.
Kinders 2-5 jaar: 1 tablet 1-2x daagliks.
Babas tot 2 jaar oud: 1 tablet 1x daagliks.

Akute of aanvanklike dosis:
Volwassenes en kinders 12 jaar en ouer: 1 tablet elke ½ tot 1 uur, tot 12x daagliks, en gaan dan voort met die gewone dosis.
Kinders 6-11 jaar: 1 tablet elke 1 tot 2 uur, tot 8x daagliks, en gaan dan voort met die gewone dosis.
Kinders 2-5 jaar: 1 tablet elke 1 tot 2 uur, tot 6x daagliks, en gaan dan voort met die gewone dosis.
Babas tot 2 jaar oud: 1 tablet elke 1 tot 2 uur, tot 4x daagliks, en gaan dan voort met die gewone dosis.

Metode van administrasie:
Die tablette moet stadig in die mond opgelos word. Vir kinders en babas word dit aanbeveel om die tablet fyn te maak en in 'n bietjie water opgelos, toe te dien.

Dit word aanbeveel dat daar vir 15 minute voordat en nadat die medikasie geneem word, nie geëet of gedrink word nie.

Indien u meer Spascupreel® neem 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 Spascupreel® te neem:
Moenie 'n dubbeldosis neem om op te maak vir vergete individuele dosisse nie.

5. Possible side effects

Spascupreel® can have side effects.

None known.

Not all side effects reported for Spascupreel® 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.

5. Moontlike newe-effekte

Spascupreel® kan newe-effekte hê.

Geen bekend nie.

Nie alle newe-effekte wat vir Spascupreel® gerapporteer is word in hierdie inligtingstuk ingesluit nie. Sou 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 opmerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief u geneesheer of apteker in kennis.

6. Storing and disposing of Spascupreel®

Keep all medicines out of the reach and sight of children.
- Store in a cool (below 25 °C) dry place.

6. Opberging van en beskikking oor Spascupreel®

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

7. Presentation of Spascupreel®

Containers of 50 tablets.

7. Aanbieding van Spascupreel®

Houers van 50 tablette.

8. Identification of Spascupreel®

White to light yellow tablets, sometimes yellowbrown dots.

8. Identifikasie van Spascupreel®

Wit tot liggeel tablette, soms met geelbruin kolletjies.

9. Registration number / Reference number

U 5510 (Act 101/1965)

9. Registrasienommer / Verwysingsnommer

U 5510 (Wet 101/1965)

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

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

10. Naam en besigheidsadres van die houer van die registrasiesertifikaat

ModHomCo (Edms) Bpk
Amsterdamstraat 96
Clubview, 0157 Centurion

11. Date of publication

August 2024

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

11. Datum van publikasie

Augustus 2024

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

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Professional Information

Spascupreel®

1. Scheduling status

Schedule 0

2. Proprietary name and dosage form

Spascupreel® Tablets

3. Composition

1 tablet cont.: Citrullus colocynthis D4 30 mg, Ammonium bromatum D4 30 mg, Atropinum sulfuricum D6 30 mg, Veratrum album D6 30 mg, Magnesium phosphoricum D6 30 mg, Gelsemium sempervirens D6 30 mg, Passiflora incarnata D2 15 mg, Amanita muscaria D4 15 mg, Chamomilla recutita D3 15 mg, Cuprum sulfuricum D6 15 mg, Aconitum napellus D6 60 mg.
Excipient: Magnesium stearate.
1 tablet contains approx. 300 mg lactose.

4. Pharmacological classification

D. 33.2. Homeopathy.

5. Pharmacological action

Action based on homeopathic principles.

6. Indications

This medicine is prepared in accordance with homeopathic principles and is proposed for use in spasms in the organs of the smooth musculature (stomach, intestine, gall bladder, uterus, urinary tract); spasticity of the striated musculature (myogelosis, hardening of the muscles).

7. Contraindications

Hypersensitivity to any of the ingredients, including excipients.

8. Warnings

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.

9. Interactions

No interactions studies have been performed.

10. Pregnancy and lactation

Safety and/or efficacy has not been established.

11. Dosage and directions for use

The usual dose is:
Adults and children 12 years and older: 1 tablet 3x daily.
Children 6-11 years: 1 tablet 2x daily.
Children 2-5 years: 1 tablet 1-2x daily.
Infants up to 2 years: 1 tablet 1x daily.

Acute or initial dosage:
Adults and children 12 years and older: 1 tablet every ½ to 1 hour, up to 12x daily, and then continue with usual dosage.
Children 6-11 years: 1 tablet every 1 to 2 hours, up to 8x daily, and then continue with usual dosage.
Children 2-5 years: 1 tablet every 1 to 2 hours, up to 6x daily, and then continue with usual dosage.
Infants up to 2 years: 1 tablet every 1 to 2 hours, up to 4x daily, and then continue with usual dosage.

Method of administration:
The tablets should be allowed to dissolve slowly in the mouth.
For children and infants, it is recommended to crush the tablet and administer it dissolved in a little water.

It is recommended not to eat or drink 15 minutes before or after taking the medication.

12. Side effects and special precautions

12.1 Side effects

None known.

12.2 Special precautions

None known.

12.3 Effects on ability to drive and use machines

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13. Known symptoms of overdosage and particulars of its treatment

None known.

14. Identification

White to light yellow tablets, sometimes yellow-brown dots.

15. Presentation

Containers of 50 tablets.

16. Storage instructions

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

17. Registration number

U 5510 (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

August 2024

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

Professionele Inligting

Tablets / Tablette

1. Skeduleringstatus

Skedule 0

2. Handelsnaam en doseervorm

Spascupreel® Tablette

3. Samestelling

1 tablet bevat: Citrullus colocynthis D4 30 mg, Ammonium bromatum D4 30 mg, Atropinum sulfuricum D6 30 mg, Veratrum album D6 30 mg, Magnesium phosphoricum D6 30 mg, Gelsemium sempervirens D6 30 mg, Passiflora incarnata D2 15 mg, Amanita muscaria D4 15 mg, Chamomilla recutita D3 15 mg, Cuprum sulfuricum D6 15 mg, Aconitum napellus D6 60 mg.
Bymiddel: Magnesiumstearaat.
1 tablet bevat ong. 300 mg laktose.

4. Farmakologiese klassifikasie

D. 33.2. Homeopatie.

5. Farmakologiese werking

Werking gebaseer op homeopatiese beginsels.

6. Indikasies

Hierdie medisyne is in ooreenstemming met homeopatiese beginsels voorberei en word voorgestel vir gebruik in spasmas in die gladdespierorgane (maag, dermkanaal, galblaas, uterus, urienweg); spastisiteit van die gestreepte spiere (miogelose, verharding van die spiere).

7. Kontra-indikasies

Hipersensitiwiteit vir enige van die bestanddele, insluitend die bymiddels.

8. Waarskuwings

Hierdie preparaat bevat natuurlike laktose. Hoewel die hoeveelheid laktose aanwesig waarskynlik nie genoegsaam is om ongemak te veroorsaak nie, moet 'n professionele gesondheidswerker geraadpleeg word in gevalle van sterk laktose-intoleransie. 'n Tydelike verergering van die bestaande simptome is moontlik na die inname van 'n homeopatiese preparaat.

9. Interaksies

Geen interaksie-studies is uitgevoer nie.

10. Swangerskap en borsvoeding

Veiligheid en/of doeltreffendheid is nie vasgestel nie.

11. Dosering en gebruiksaanwysings

Die gewone dosis is:
Volwassenes en kinders 12 jaar en ouer: 1 tablet 3x daagliks.
Kinders 6-11 jaar: 1 tablet 2x daagliks.
Kinders 2-5 jaar: 1 tablet 1-2x daagliks.
Babas tot 2 jaar oud: 1 tablet 1x daagliks.

Akute of aanvanklike dosis:
Volwassenes en kinders 12 jaar en ouer: 1 tablet elke ½ tot 1 uur, tot 12x daagliks, en gaan dan voort met die gewone dosis.
Kinders 6-11 jaar: 1 tablet elke 1 tot 2 uur, tot 8x daagliks, en gaan dan voort met die gewone dosis.
Kinders 2-5 jaar: 1 tablet elke 1 tot 2 uur, tot 6x daagliks, en gaan dan voort met die gewone dosis.
Babas tot 2 jaar oud: 1 tablet elke 1 tot 2 uur, tot 4x daagliks, en gaan dan voort met die gewone dosis.

Metode van administrasie:
Die tablette moet stadig in die mond opgelos word.
Vir kinders en babas word dit aanbeveel om die tablet fyn te maak en in 'n bietjie water opgelos, toe te dien.

Dit word aanbeveel dat daar vir 15 minute voordat en nadat die medikasie geneem word, nie geëet of gedrink word nie.

12. Newe-effekte en spesiale voorsorgmaatreëls

12.1 Newe-effekte

Geen bekend nie.

12.2 Spesiale voorsorgmaatreëls

Geen bekend nie.

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

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

Geen bekend nie.

14. Identifikasie

Wit tot liggeel tablette, soms met geelbruin kolletjies.

15. Aanbieding

Houers van 50 tablette.

16. Opbergingsinstruksies

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

17. Registrasienommer

U 5510 (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

Augustus 2024

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

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