

Viburcol[®] N

Suppositories / Setpille

Read all of this leaflet carefully because it contains important information for you

Viburcol[®] N is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use Viburcol[®] N carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Viburcol[®] N 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 Viburcol[®] N contains

Each suppository contains:

The active substances are: Chamomilla recutita D1 1,100 mg; Atropa belladonna D2 1,100 mg; Plantago major D3 1,100 mg; Pulsatilla pratensis D2 2,200 mg; Calcium carbonicum Hahnemannni D8 4,400 mg.

The other ingredient is: Hard fat.

2. What Viburcol[®] N 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 infants and children in conditions of restlessness with or without fever; symptomatic treatment of common infections.

3. Before you use Viburcol[®] N

Do not use Viburcol[®] N:

- if you are hypersensitive (allergic) to
 - active substances or any of the other ingredients of Viburcol[®] N
 - to Chamomilla or botanicals of the daisy (compositae) family.

Warnings

If symptoms persist or worsen you should consult a doctor or healthcare professional.

In the first year of life, you should consult a doctor in case of ongoing fever above 38 °C. Toddlers should be presented to a doctor from the second day of illness at the latest.

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.

Using other medicines with Viburcol[®] N:

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

4. How to use Viburcol[®] N

Do not share medicines prescribed for you with any other person.

Always use Viburcol[®] N exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

Remove suppository from plastic foil.

In acute disorders, insert one suppository rectally and repeat on several occasions; after alleviation of symptoms, insert one suppository 2-3 times daily.

For infants (from the first day of life) up to six months of age, do not use more than one suppository twice daily.

If you use more Viburcol[®] N than you should:

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to use Viburcol[®] N:

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

5. Possible side effects

Viburcol[®] N can have side effects.

Allergic skin reactions may occur in rare cases.

Not all side effects reported for Viburcol[®] N are included in this leaflet. Should your general health worsen while using 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 Viburcol[®] N

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

The suppositories should only be subjected to temperatures below 25 °C, since higher temperatures will cause the suppository mass to soften and melt.

7. Presentation of Viburcol[®] N

Packs containing 12 suppositories.

8. Identification of Viburcol[®] N

White to yellow white (ivory coloured), torpedo-shaped suppositories with a smooth surface.

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

April 2023

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

Lees die hele inligtingstuk noukeurig aangesien dit belangrike inligting bevat

Viburcol[®] N is sonder 'n doktersvoorskrif beskikbaar om 'n ligte siektetoestand te behandel. Nogtans moet Viburcol[®] N versigtig gebruik word om die beste resultate te verkry.

- Hou hierdie inligtingstuk. U mag dit weer moet lees.
- Moenie Viburcol[®] N 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 Viburcol[®] N bevat

Elke setpil bevat:

Die aktiewe bestanddele is: Chamomilla recutita D1 1,100 mg; Atropa belladonna D2 1,100 mg; Plantago major D3 1,100 mg; Pulsatilla pratensis D2 2,200 mg; Calcium carbonicum Hahnemannni D8 4,400 mg.

Die ander bestanddeel is: Harde vet.

2. Waarvoor Viburcol[®] N gebruik word

Farmakologiese klassifikasie: D.33.2. Homeopatie.

Dissipline van die medisyne: Homeopatie

Hierdie medisyne is in ooreenstemming met homeopadiese beginsels voorberei en word voorgestel vir gebruik in babas en kinders vir toestande van rusteloosheid met of sonder koors; simptomatiese behandeling van algemene infeksies.

3. Voordat u Viburcol[®] N gebruik

Moenie Viburcol[®] N gebruik:

- indien u hipersensitief (allergies) is vir
 - die aktiewe bestanddele of enige van die ander bestanddele van Viburcol[®] N
 - vir Chamomilla of plante van die daisy (madeliefie) (compositae) familie.

Waarskuwings

Indien simptome voortduur of vererger moet u 'n dokter of gesondheidswerker raadpleeg.

Kontak u geneesheer indien u baba onder 1 jaar is en met 'n aanhoudende koors bo 38 °C voordo. Dit word aanbeveel dat u 'n geneesheer raadpleeg indien u kleuter se kondisie nie ten minste binne die eerste dag verbeter nie.

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.

Die neem van ander medisyne met Viburcol[®] N:

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

4. Hoe om Viburcol[®] N te gebruik

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

Gebruik Viburcol[®] N altyd presies soos wat dit vir u voorgeskryf is. Raadpleeg u geneesheer of apteker indien u onseker is.

Die gewone dosis is:

Verwyder setpil vanuit die plastiekfoelie.

In akute verstourings, plaas een setpil in die anus en herhaal verskeie kere; nadat die simptome verlig is, gebruik een setpil 2-3 maal per dag.

Vir babas (vanaf die eerste lewensdag to ses maande oud), moenie meer as een setpil twee maal per dag gebruik nie.

Indien u meer Viburcol[®] N 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 Viburcol[®] N te gebruik:

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

5. Moontlike nuwe-effekte

Viburcol[®] N kan nuwe-effekte hê.

Allergiese velreaksies mag in uitsonderlike gevalle voorkom.

Nie alle nuwe-effekte wat vir Viburcol[®] N gerapporteer is, word in hierdie inligtingstuk ingesluit nie. Indien u algemene gesondheid vererger terwyl hierdie medisyne gebruik word, 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 Viburcol[®] N

Hou alle medisyne buite die bereik en sig van kinders.

Die setpille moet slegs aan temperature onder 25 °C blootgestel word aangesien hoër temperature daartoe sal lei dat die setpilmasse sag word en smelt.

7. Aanbieding van Viburcol[®] N

Pakkies bevattende 12 setpille.

8. Identifikasie van Viburcol[®] N

Wit tot geelwit (ivoorkleurige) torpedo-gevormde setpille met 'n gladde oppervlak.

9. Registrasienommer / Verwysingsnommer

Om deur die SAHPRA toegeken te word.

10. Naam en besigheidsadres van die houër van die registrasiesertifikaat

ModHomCo (Edms) Bpk
Amsterdamstraat 96
Clubview, 0157 Centurion

11. Datum van publikasie

April 2023

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

-Heel

Viburcol[®] N

Suppositories / Setpille

1. Scheduling status

Schedule 0

2. Proprietary name and dosage form

Viburcol[®] N Suppositories

3. Composition

Each suppository contains: Chamomilla recutita D1 1,100 mg; Atropa belladonna D2 1,100 mg; Plantago major D3 1,100 mg; Pulsatilla pratensis D2 2,200 mg; Calcium carbonicum Hahnemannii D8 4,400 mg.
Excipient: Hard fat.

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 infants and children in conditions of restlessness with or without fever; symptomatic treatment of common infections.

7. Contraindications

Hypersensitivity to Chamomilla or botanicals of the daisy (compositae) family or to one or more of the ingredients.

8. Warnings

None.

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

Remove suppository from plastic foil.
In acute disorders, insert one suppository rectally and repeat on several occasions; after alleviation of symptoms, insert one suppository 2-3 times daily.
For infants (from the first day of life) up to six months of age, do not use more than one suppository twice daily.

12. Side effects and special precautions

12.1 Side Effects

Allergic skin reactions may occur in rare cases.

12.2 Special Precautions

12.3 Effects on ability to drive and use machines

No effects on the ability to drive and use machines have been reported, and none are expected due to the homeopathic dilutions.

13. Known symptoms of overdose and particulars of its treatment

None known.

14. Identification

White to yellow white (ivory coloured), torpedo-shaped suppositories with a smooth surface.

15. Presentation

Packs containing 12 suppositories.

16. Storage instructions

The suppositories should only be subjected to temperatures below 25 °C, since higher temperatures will cause the suppository mass to soften and melt.
Keep out of 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

April 2023

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

1. Skeduleringsstatus

Skedule 0

2. Handelsnaam en doseervorm

Viburcol[®] N Setpille

3. Samestelling

Elke setpil bevat: Chamomilla recutita D1 1,100 mg; Atropa belladonna D2 1,100 mg; Plantago major D3 1,100 mg; Pulsatilla pratensis D2 2,200 mg; Calcium carbonicum Hahnemannii D8 4,400 mg.
Bymiddel: Harde vet.

4. Farmakologiese klassifikasie

D.33.2. Homeopatie.

5. Farmakologiese werking

Werkings gebaseer op homeopatiese beginsels.

6. Indikasies

Hierdie medisyne is in ooreenstemming met homeopatiese beginsels voorberei en word voorgestel vir gebruik in babas en kinders in gevalle van rusteloosheid met of sonder koors; simptome behandeling van algemene infeksies.

7. Kontra-indikasies

Hypersensitiwiteit vir Chamomilla of plante van die daisy (madeliefie) familie of vir een of meer van die bestanddele.

8. Waarskuwings

Geen.

9. Interaksies

Geen interaksie-studies is uitgevoer nie.

10. Swangerskap en borsvoeding

Veiligheid en/of doeltreffendheid is nie vasgestel nie.

11. Dosing en gebruiksaanwysings

Verwyder die setpil vanuit die plastiekfoelie. In akute verstuurings, plaas een setpil in die anus en herhaal verskeie kere; na verligting van die simptome, plaas een setpil in die anus 2-3 maal per dag. Vir babas (vanaf die eerste lewensdag tot ses maande ouderdom), moenie meer as een setpil twee maal per dag gebruik nie.

12. Nuwe-effekte en spesiale voorsorgmaatreëls

12.1 Nuwe-effekte

Allergiese velreaksies mag in uitsonderlike gevalle voorkom.

12.2 Spesiale Voorsorgmaatreëls

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

Geen effekte op die vermoë om te bestuur en masjiene te gebruik, is aangemeld nie en geen uitwerking word verwag nie as gevolg van die homeopatiese verdunnings.

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

Geen bekend nie.

14. Identifikasie

Wit tot geelwit (ivoorkleurige), torpedo-gevormde setpille met 'n gladde oppervlak.

15. Aanbieding

Pakkies bevattende 12 setpille.

16. Opbergingsinstruksies

Die setpille moet slegs aan temperature onder 25 °C blootgestel word aangesien hoër temperature daartoe sal lei dat die setpilmasse sag word en smelt.
Hou buite die bereik van kinders.

17. Registrasienuommer

Om deur die SAHPRA toegeken te word.

18. Naam en besigheidsadres van die houër van die registrasiesertifikaat

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

19. Datum van publikasie van hierdie professionele inligting

April 2023

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