

sinulex^{FORTE}

Natural sinus, colds & flu support!

SCHEDULING STATUS

Combination complimentary medicine: D.10.1 (Multi-Vitamin and Herbal/Plant Extracts)

PROPRIETARY NAME AND DOSAGE FORM

Sinulex Forte Capsules 3's, 10's, 30's

COMPOSITION

THE ACTIVE SUBSTANCES ARE:

Pelargonium Sidooides Extract PE60 <i>root extract as 20 mg of a 5:1 extract / standardised to > 60 ppm Umckalin</i>	100 mg
Horseradish Extract <i>root extract 50 mg of 4:1 extract</i>	200 mg
L-Ascorbic Acid (Vitamin C)	300 mg
Zinc Sulfate <i>equivalent to 5 mg elemental Zinc</i>	21.8 mg
Vitamin D3 (7,5 µg Cholecalciferol)	300 iu

THE OTHER INGREDIENTS ARE:

Microcrystalline cellulose, Magnesium Stearate, Pirosil

PHARMACOLOGICAL ACTION

Pelargonium Sidooides root extract is a clinically and pharmacologically well documented modern plant based medicine for upper respiratory tract infections. Unlike other sinusitis, cough, cold and flu remedies, this unique extract contained in the preparation Sinulex Forte Capsules not only relieves symptoms, but also shortens the duration of the illness itself. It has a unique pharmacological profile which is ideal for the treatment of respiratory tract infections: It activates anti-viral defences, fights bacteria, and is a mucolytic. Horseradish has shown to have a strong mucolytic action. Vitamin C supports a healthy immune system. Cholecalciferol (Vitamin D3) supports a strong immune system. Zinc Sulfate is the best form of Zinc for preventing and treating colds. Clinical studies showed that zinc significantly shortens the duration of symptoms during rhinovirus infections.

Indication:

Sinulex's comprehensive formula supports the body's ability to naturally deal with allergens, cold, flu and sinusitis for healthier airways and a clear head.

CONTRAINDICATIONS

Known hypersensitivity to any of the ingredients mentioned under "COMPOSITION" See "Pregnancy and Lactation"

WARNINGS AND SPECIAL PRECAUTIONS

Allergic reactions to any of the ingredients mentioned.

INTERACTIONS

No interactions studies have been performed.

Take Sinulex under the supervision of your healthcare practitioner while using blood thinning medication (e.g. Warfarin).

PREGNANCY AND LACTATION

Safety during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Acute Dosage:

Adults and children above 12:

Take 1 capsule three times daily.

Children 6 – 12 years:

Take 1 capsule twice daily.

It is recommended to take this dosage for at least 5 consecutive days.

Chronic Dosage:

Adults and children above 12 years:

Take 1 capsule twice daily.

Children 6 -12 years: Take 1 capsule daily,

Or as prescribed by your healthcare professional.

Do not exceed the recommended daily dosage.

SIDE EFFECTS

Known hypersensitivity (allergies) to any of the mentioned ingredients.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Treatment is supportive and symptomatic.

IDENTIFICATION

3, 10 or 30 Yellow & white capsules containing a grey/white powder packed in blister packs.

PRESENTATION

3's, 10's and 30's Capsules in a blister packed in a box.

STORAGE INSTRUCTIONS

Keep in a dry, cool place below 25 °C.

Protect from light.

REGISTRATION NUMBER

Will be allocated on registration

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Tara Pharmaceuticals (Pty) Ltd

Unit 9, Fish Eagle Park

Old Paardevlei Road

Somerset West

7130

South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT

25 August 2014

REGISTRATION DATE: 14-08-2008

PATIENT INFORMATION LEAFLET

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

This medicine is available without prescription. However, you still need to use Sinulex Forte Capsules carefully to obtain the best results.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must consult a doctor if your symptoms worsen or do not improve.
- If you notice any side effects, please tell your doctor or pharmacist.

In this leaflet:

1. What Sinulex Forte Capsules are and what they are used for
2. Before you take Sinulex Forte Capsules
3. How to take Sinulex Forte Capsules
4. Possible side effects
5. Storing Sinulex Forte Capsules
6. Further information

1. What Sinulex Forte Capsules are and what they are used for:

Sinulex Forte Capsules contain Pelargonium Sidooides extract, Horseradish extract and Ascorbic acid to help relieve colds, flu, sinusitis, and seasonal allergy symptoms.

The active ingredients in Sinulex Forte Capsules have strong anti-inflammatory, antiviral, antibacterial and antifungal properties that may help to reduce inflammation and fight infections, bacteria and viruses that can cause respiratory infections and congestion.

2. Before you take Sinulex Forte Capsules:

Do not take this medicine if:

- you are allergic (hypersensitive) to any of the ingredients in Sinulex Forte Capsules.
- it is for a child younger than 6 years.

Taking other medicines:

Sinulex Forte Capsules are not known to interact with other medicines.

Pregnancy and Breastfeeding:

Sinulex Forte Capsules safety has not been established during pregnancy or breastfeeding.

3. How to take Sinulex Forte Capsules:

Sinulex Forte Capsules can be used by adults, the elderly and by children over 6 years old.

Acute Dosage:

Adults and children above 12:

Take 1 capsule three times daily.

Children 6 – 12 years:

Take 1 capsule twice daily.

It is recommended to take this dosage for at least 5 consecutive days.

Chronic Dosage:

Adults and children above 12 years:

Take 1 capsule twice daily.

Children 6 -12 years: Take 1 capsule daily,

Or as prescribed by your healthcare professional.

Do not exceed the recommended daily dosage.

If the condition does not improve or becomes worse, consult your doctor, nurse or pharmacist.

If you miss a dose:

Take a capsule as soon as you remember then adjust the time for the next dose. Do not take two capsules at the same time to make up for the missed dose.

If you take too many:

Do not take more than 3 capsules in a 24-hour period. Taking too much can cause an upset stomach. If you feel discomfort, tell your doctor or your pharmacist.

4. Possible side effects:

No side effects have been reported for Sinulex Forte Capsules.

If you feel any side effects or unwell after taking Sinulex Forte Capsules, stop using it immediately and tell your doctor or pharmacist straightaway.

5. Storing Sinulex Forte capsules:

Store at or 25°C in a dry place to protect it against moisture. Keep out of the reach and sight of children. Do not use Sinulex Forte Capsules after the date (month and year) printed after "USE BY" on the pack. If the expiry date has passed.

6. Further information:

Sinulex Forte Capsules are a pale grey/white powder, packed in yellow & white capsules in blister packs.

Active substances:

Each capsule contains.

Pelargonium Sidooides Extract PE60 <i>root extract as 20 mg of a 5:1 extract / standardised to > 60 ppm Umckalin</i>	100 mg
Horseradish Extract <i>root extract 50 mg of 4:1 extract</i>	200 mg
L-Ascorbic Acid (Vitamin C)	300 mg
Zinc Sulfate <i>equivalent to 5 mg elemental Zinc</i>	21.8 mg

Vitamin D3 (7,5 µg Cholecalciferol)

300 iu

Other ingredients:

Microcrystalline cellulose, Magnesium Stearate, Pirosil

Tara Pharmaceuticals

Unit 9, Fish Eagle Park

Old Paardevlei road

Somerset West

7130

Helpdesk: 086 111 8272

This medicine has not been evaluated by SAHPRA. This medicine is not intended to diagnose, treat, cure or prevent any disease.

NUPIN096/04

sinulex FORTE

Natural sinus, colds & flu support!

SKEDULERINGSSTATUS

Kombinasie KOMPLIMENTêRE Medisyne: D.10.1 (Multi-Vitamiën en Krui/Plant ekstrak)

HANDELSNAAM EN DOSSEERVORM

Sinulex Forte Kapsules 3's, 10's, 30's

SAMESTELLING

DIE AKTIEWE BESTANDELE IS:

Pelargonium Sidoides Ekstrak PE60	100 mg
wortel ekstrak 20 mg van 'n 5:1 ekstrak / gestandaardiseer om > 60 ppm Umckalin	
Peperwortel ekstrak	200 mg
wortel ekstrak 50 mg van 'n 4:1 ekstrak	
L-Askorbiensuur (Vitamiën C)	300 mg
Sink Sulfaat	21.8 mg
<i>gelykstaande aan 5 mg elementaal Sink</i>	
Vitamiën D3 (7,5 µg Cholekalsiferol)	300 iu

DIE ANDER BESTANDELE IS:

Mikrokristallieke sellulose, Magnesiumstearaat, Pirosoil

FARMAKOLOGIESE WERKING

Pelargonium Sidoides wortel ekstrak. Pelargonium Sidoides is 'n plant ekstrak medikasie wat klinies en farmalogies ondersteun word deur goed gedokumenteerde moderne mediese studies vir respiratoriese lugweg infeksies. Uniek anders as ander sinusitis, hoës, verkoue en griep medikasies verlig die Perargonium ekstrak in Sinulex Forte kapsules nie net die simptome nie, maar verkort ook die tyd en ernstigheid van die siekte, dus verminder dit die tyd afwesig van skool en werk. Pelargonium het 'n unieke farmakologiese profiel wat ideaal is vir die behandeling van respiratoriese infeksies. Dit aktiveer anti-virale beskermings aktiwiteite, veg bakterie en het 'n sterk mukolitiese effek. Peperwortel ekstrak het sterk mukolitiese werking. Vitamiën C ondersteun 'n gesonde immuun sisteem. Cholekalsiferol (Vitamiën D3) ondersteun 'n sterk immuunstelsel. Sink Sulfaat is die beste vorm van Sink om verkoue te voorkom en te behandel. Kliniese studies het getoon dat Sink die duur van die simptome tydens rhinovirusinfeksies aansienlik verkort.

Sinulex is geformuleer met natuurlike bestanddele wat verligting van infektiewe, allergiese en inflamatoriese verwante toestande ondersteun. Dit is veral ondersteunend teenoor lug oorgegrade stowwe en infeksies, wat jou oë, neus en keel kan irriteer.

INDIKASIES

Sinulex Forte kapsules se omvattende formule ondersteun die liggaam se vermoë om infeksies en allergie natuurlik te hanteer vir 'n gesonder lugweg .

KONTRA-INDIKASIE

Hipersensitiwiteit teenoor enige van die bestanddele, "SAMESTELLING" sien "SWANGERSKAP EN LAKTASIE"

WAARSKUWINGS EN SPESIALE VOORSORGMATREELS

Allergiese reaksie teenoor enige van die bestanddele

INTERAKSIES

Geen interaksie studies is uitgevoer.

Neem Sinulex Forte kapsules onder die toesig van jou gesondheidsorg praktisyn terden die gebruik van bloedverdunding medikasie (bv. Warfarine).

SWANGERSKAP EN LAKTASIE

Veiligheid tydens swangerskap en laktasie is nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS

Akute dosis:

Volwassenes en kinders bo 12:

Neem een kapsule drie maal per dag.

Kinders 6 – 12 jaar:

Neem een kapsule twee keer per dag.

Dit word aanbeveel om hierdie dosis vir ten minste 5 agtereenvolgende dae te neem.

Chroniese dosis:

Volwassenes en kinders bo 12 jaar:

Neem een kapsule twee keer per dag.

Kinders 6 – 12 jaar:

Neem een kapsule per dag.

Of soos voorgeskryf deur jou gesondheids praktisyn.

Moet nie meer as die daaglikse dosis oorskry nie.

NEWE-EFFEKTE

Bekende hipersensitiwiteit (allergie) na enige van die bestanddele.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE

3's, 10's en 30's Geel en wit kapsules wat 'n grys/wit poeier bevat in blister verpak.

AANBIEDING

3's, 10's en 30's Kapsules in blister verpakings , in 'n boks verpak.

BERGINGSINSTRUKSIES

Hou in 'n droë koel plek onder 25°C

Beskerm teen lig.

REGISTRASIENOMMER

Sal toegeken word by registrasie

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

Tara Pharmaceuticals (Pty) Ltd

Unit 9, Fish Eagle Park

Old Paardevlei Road

Somerset Wes

7130

Suid Afrika

DATUM VAN PUBLIKASIE VAN DIE VOUBLIJET

25 Augustus 2014

REGISTRASIE DATUM: 14-08-2008

PASIENTINLIGTINGSBLAADJIE

Lees hierdie blaadjie sorgvuldig deur, want dit bevat belangrike inligting vir u.

Hierdie medisyne is beskikbaar sonder 'n voorskrif. Egter moet jy Sinulex Forte Kapsules sorgvuldig gebruik om die beste resultate daaruit te kry.

- Hou hierdie inligtingsblaadjie, jy mag hom dalk weer moet lees.
- Vra jou apteker as jy meer inligting of advies nodig het.
- Jy moet jou dokter kontak as jou simptome vererger of nie verbeter nie.
- As jy enige nuwe-effekte sien of ervaar, vertel jou dokter of apteker daarvan.

In hierdie inligtingsblaadjie :

- 1) Wat Sinulex Forte Kapsules is en waarvoor dit gebruik word
- 2) Voordat jy Sinulex Forte Kapsules neem
- 3) Sinulex Forte Kapsules te neem
- 4) Moontlike nuwe-effekte
- 5) Berging van Sinulex Forte Kapsules
- 6) Verdere inligting

1. Wat Sinulex Forte Kapsules is en waarvoor dit gebruik word.

Sinulex Forte Kapsules bevat Pelargonium Sidoides ekstrak, Askorbien Suur (Vitamiën C) en Peperwortel Ekstrak om die simptome, pyn en ongemak te verlig van verkoue, griep en sinusitis. Die aktiewe bestanddele in Sinulex Forte Kapsules het sterk anti-inflamatoriese, anti-virale, anti-bakteriese en antifungale eienskappe en help om inflammasie en infeksies wat seer keel kan veroorsaak te beveg.

2. Voor dat jy Sinulex Forte Kapsules neem

Moenie hierdie medisyne neem as:

Jy allergies of hipersensitief is vir een van die bestanddele in Sinulex Forte Kapsules

Dit vir 'n kind onder 6 jaar oud is nie.

Die neem van ander medisyne:

Sinulex Forte Kapsules is nie bekend om met ander medikasie te interveer nie.

Swangerskap en borsvoeding:

Sinulex Forte Kapsules se veiligheid is nog nie vas gestel gedurende swangerskap en borsvoeding nie.

3. Hoe om Sinulex Forte Kasules te neem:

Akute dosis:

Volwassenes en kinders bo 12:

Neem een kapsule drie maal per dag.

Kinders 6 – 12 jaar:

Neem een kapsule twee keer per dag.

Dit word aanbeveel om hierdie dosis vir ten minste 5 agtereenvolgende dae te neem.

Chroniese dosis:

Volwassenes en kinders bo 12 jaar:

Neem een kapsule twee keer per dag.

Kinders 6 – 12 jaar:

Neem een kapsule per dag.

Of soos voorgeskryf deur jou gesondheids praktisyn.

Moet nie meer as die daaglikse dosis oorskry nie.

As die kondisie nie verbeter en net erger word, praat met jou dokter, verpleegster of apteker.

As jy 'n dosis mis:

Neem 'n kapsule so gou as wat jy onthou, pas die tyd vir die volgende dosis net aan.

Moenie twee kapsules op dieselfde tyd neem om die gemigde dosis op te maak nie.

As jy te veelgeneem het:

Moenie meer as 3 kapsules in 'n 24 uur periode neem nie. Teveel kan lei tot 'n ontstoke maag. As u ongemak voel, vertel u dokter of apteker daarvan.

4. Moontlike nuwe-effekte:

Geen nuwe-effekte is al gerapporteer van Sinulex Forte Kapsules nie.

As jy enige nuwe-effekte of ongesteldheid voel na die neem van Sinulex Forte Kapsules kontak jou dokter of apteker onmiddelik.

5. Berging van Sinulex Forte Kapsules:

Stoor by of benede 25°C. Stoor op 'n droë plek om dit teen vog te beskerm. Hou buite bereik en sig van kinders. Moenie Sinulex Forte Kapsules na die verval datum gebruik nie, gemerk "GEBRUIK VOOR" datum.

6. Verdere inligting:

Sinulex Forte Kapsules is 'n lig grys/wit kleurige poeier verpak in geel en wit kapsules in 'n blister pak .

Daar is 3, 10 of 30 kapsules in 'n boks.

AKTIEWE STOWWE:

Elke kapsule bevat:

Pelargonium Sidoides Ekstrak PE60	100 mg
wortel ekstrak 20 mg van 'n 5:1 ekstrak / gestandaardiseer om > 60 ppm Umckalin	
Peperwortel ekstrak	200 mg
wortel ekstrak 50 mg van 'n 4:1 ekstrak	
L-Askorbiensuur (Vitamiën C)	300 mg
Sink Sulfaat	21.8 mg
<i>gelykstaande aan 5 mg elementaal Sink</i>	
Vitamiën D3 (7,5 µg Cholekalsiferol)	300 iu

ANDER BESTANDELE:

Mikrokristallieke sellulose, Magnesiumstearaat, Pirosoil

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7130

Hulp lyn: 086 111 8272

Hierdie medisyne is nie deur SAHPRA geëvalueer nie. Hierdie medisyne beoog nie om enige siekte te diagnoseer, te genees of te voorkom nie.

NUPIN096/04