



English

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:**

S0

Sinulex® Forte Syrup**Strength**858 mg per 7 mL; or
12 257 mg per 100 mL**Pharmaceutical form**

Liquid, syrup, oral

Active substances

| | |
|-----------------------------------|--------|
| Cowslip flower extract | 198 mg |
| Field sorrel leaf extract | 198 mg |
| Elderflower extract | 198 mg |
| Verbena leaf extract | 198 mg |
| Yellow gentian root extract | 66 mg |

Sugar-free.

Contains sweetener:

- Sorbitol2828 mg / 7 mL

This product is a Complementary Medicine (Category D33.7); and is identified according to its discipline as a Combination Product; which is not registered by the Authority.

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

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

Sinulex® Forte Syrup is available without a doctor's prescription, for you to treat a mild illness or maintain your health. Nevertheless, you still need to use Sinulex® Forte Syrup carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Sinulex® Forte Syrup with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What Sinulex® Forte Syrup is and what it is used for.
2. What you need to know before you use Sinulex® Forte Syrup.
3. How to take Sinulex® Forte Syrup.
4. Possible side effects.
5. How to store Sinulex® Forte Syrup.
6. Contents of the pack and other information.

1. What Sinulex® Forte Syrup is and what it is used for.

Sinulex® Forte Syrup supports the immune system to deal with coughs, allergens, colds, flu, and sinusitis for better overall health. Due to the active substances, Sinulex® Forte Syrup is indicated for therapeutic use only from the age of 2 years and older. These active substances are useful for symptomatic relief of sinus pressure, sinus congestion, post-nasal drip, colds, and flu symptoms, by supporting the respiratory and immune systems. Its active substances may also support the immune function of those who are asymptomatic as a low-risk health supplement. It is a health supplement that contains important expectorant, anti-bacterial, anti-microbial, anti-inflammatory, and sedative properties and can be used to support the respiratory tract, supporting the paranasal sinuses. Sinulex® Forte Syrup is indicated for self-administration as a low-risk health supplement, although only a healthcare provider may indicate it as an adjunct treatment to an existing treatment regimen for individual persons. It is not indicated as an alternative therapy to replace

conventional medicines or any other treatments prescribed by a healthcare provider. Sinulex® Forte Syrup is a medicinal health supplement not intended (nor indicated) for maintenance or alternative maintenance therapy, but rather for symptomatic relief when this medicine is needed. It is not indicated as a cure-all or monotherapy for serious conditions because Sinulex® Forte Syrup is not intended (nor indicated) to diagnose, treat, prevent, or cure diseases. It is strictly indicated for symptomatic relief as a low-risk supportive supplement.

2. What you need to know before you use Sinulex® Forte Syrup.**Do not take Sinulex® Forte Syrup:**

- if you are hypersensitive (allergic) to the active substances, or any of the other ingredients Sinulex® Forte Syrup (listed in section 6).
- if you are on hypoglycemic medication since this medicine also has hypoglycemic properties (see 'Warnings and precautions').
- if you have a surgery or dental procedure scheduled, for at least two weeks prior.
- without consulting your healthcare provider if you have an existing treatment regimen.

Warnings and precautions

Special care should be taken with Sinulex® Forte Syrup:

- if you are already on prescription hypoglycemic medication because of the risk of excess hypoglycemic effects.
- if you have diabetes or are using antidiabetic medication.
- when pregnant or breastfeeding because safety during pregnancy and lactation has not been established.

Children

Do not give Sinulex® Forte Syrup to children who are below the age of 2 years because it is unlikely to be safe. Do not attempt to reconstitute the syrup. The recommended dosages are specifically calculated to be safe for persons above the age of 2 years only. Keep out of the reach of children.

Other medicines and Sinulex® Forte Syrup

Always tell your health care provider if you are taking any other medicine. Other may interfere with or potentiate the effects of Sinulex® Forte Syrup and vice versa.

Sinulex® Forte Syrup with alcohol

We do not recommend that you use Sinulex® Forte Syrup with alcohol as this may only further impair the benefits that can be derived from the active substances.

Pregnancy and breastfeeding

Safety for use during pregnancy and breastfeeding has not been established. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

No undesirable effects on driving and using machines have been reported with Sinulex® Forte Syrup. It is not always possible to predict to what extent a medicine may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which a medicine affects them.

Sinulex® Forte Syrup contains the following excipients:

- Sorbitol 2828 mg
- Other inactive substances:
 - Citric acid
 - Carmellose sodium
 - Tutti frutti flavour (CR-048)
 - Glycerine
 - Potassium sorbate
 - Sodium benzoate
 - Hydrogen dioxide

3. How to take Sinulex® Forte Syrup.

Do not share medicines prescribed for you with any other person. Always take Sinulex® Forte Syrup exactly as described in this leaflet

or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist, or nurse if you are not sure.

- The usual dose is 1½ teaspoon or 7 mL of syrup, 3 times daily, which is the daily equivalent of 3 times a full single dose, for **adolescents over the age of 12, adults, and the elderly**; and is the maximum recommended daily and/or total dose.
- The usual dose is ¾ teaspoon or 3.5 mL of syrup, 3 times daily, which is the daily equivalent of 1.5 times a full single dose, for **children over the age of 6 years**; and is the maximum recommended daily and/or total dose.
- The usual dose is ½ teaspoon or 2.1 mL of syrup, 3 times daily, which is the daily equivalent of 1 full single dose, for **children above the age of 2 years**; and is the maximum recommended daily and/or total dose.
- Use a measuring spoon or the measuring cup provided to ensure safe intake/swallowing of the medicine.
- Only take this product orally.

If you take more Sinulex® Forte Syrup than you should

- you may experience gastrointestinal discomfort.
- In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use Sinulex® Forte Syrup

- then do not exceed the maximum recommended daily and/or total dose; and
- do not use a double dose to make up for forgotten individual doses.

4. Possible side effects.

Sinulex® Forte Syrup can have side effects. Not all side effects reported for Sinulex® Forte Syrup are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Sinulex® Forte Syrup, please consult your health care provider for advice.

If any of the following happens, stop taking/using Sinulex® Forte Syrup and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 'swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing',
- 'rash or itching',
- 'fainting'

These are all very serious side effects and could be signs of an allergic reaction or hypersensitivity to Sinulex® Forte Syrup. You may need urgent medical attention or hospitalization.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Sinulex® Forte Syrup.

5. How to store Sinulex® Forte Syrup.

Store all medicines out of reach of children.

Store in a cool, dry place at temperatures of 59-77° F, equivalent to 15-25° C, and with ambient humidity between 35% and 65%.

Do not refrigerate or freeze.

Store in the original package or container.

Protect from direct sunlight and moisture.

Do not use it after the expiry date stated on the label.

Do not use Sinulex® Forte Syrup if you notice abnormal appearance or unpleasant odor, as the product may be expired or was improperly stored.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems.

Please recycle the empty containers.

6. Contents of the pack and other information.

What Sinulex® Forte Syrup contains

The active substances are as listed at the start of this leaflet. The other ingredients are listed as excipients (see section 2) in this leaflet.

What Sinulex® Forte Syrup looks like and contents of the pack

Sinulex® Forte Syrup comes in cap-sealed bottles of 100 mL syrup per bottle. The active substances provide a total of 858 mg per 7 mL of syrup. Sinulex® Forte Syrup has a 7 mL of syrup dosage form with a specific appearance: Liquid, syrup, opaque maple color, pourable viscosity, markings not applicable. The carton acts as the secondary packaging for storage, also showing the proper labeling.

Holder of Certificate of Registration

Tara Pharmaceuticals (Pty) Ltd
36 Sovereign Drive, Route 21 Corporate Park, Irene, Gauteng, 0062, South Africa

Application number

DCFS-db4f9a
Act 101/1965

Access to corresponding Professional Information

<https://www.tarapharmaceuticals.com/items>



Afrikaans

PASIËNTINLIGTINGS-PAMFLET**SKEDULERINGSSTATUS:**

S0

Sinulex® Forte Stroop**Sterkte**

858 mg per 7 mL; of
12 257 mg per 100 mL

Farmaseutiese vorm

Vloeistof, stroop, orale

Aktiewe bestanddele

| | |
|-----------------------------------|--------|
| Koeislopbloem ekstrak | 198 mg |
| Veldsuringblaar ekstrak | 198 mg |
| Vierbloem ekstrak | 198 mg |
| Verbena-blaar ekstrak | 198 mg |
| Geel gentiaan wortel ekstrak..... | 66 mg |

Suikervry.

Bevat versoeter:

- Sorbitol2828 mg / 7 mL

Hierdie produk is 'n Komplimentêre Medisyne (Kategorie D33.7); en word geïdentifiseer volgens sy dissipline as 'n Kombinasie Produk; which is not registered by the Owerheid.

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

Lees hierdie hele pamflet noukeurig deur omdat dit belangrike inligting vir u bevat

Sinulex® Forte Stroop is beskikbaar sonder 'n dokter se voorskrif, sodat jy 'n ligte siekte kan behandel of jou gesondheid kan handhaaf. Maar jy moet nog steeds Sinulex® Forte Stroop ersigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie pamflet. Miskien moet jy dit weer lees.
- Moenie Sinulex® Forte Stroop deel met enige ander persoon nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies nodig het.
- U moet 'n dokter sien as u simptome vererger of nie na 7 dae verbeter nie.

Wat is in hierdie pamflet

- Wat Sinulex® Forte Stroop is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy Sinulex® Forte Stroop gebruik.
- Hoe om Sinulex® Forte Stroop te neem.
- Moontlike nuwe-effekte.
- Hoe om Sinulex® Forte Stroop te stoor.
- Inhoud van die pak en ander inligting.

7. Wat Sinulex® Forte Stroop is en waarvoor dit gebruik word.

Sinulex® Forte Stroop ondersteun die immuunstelsel om hoë, allergene, verkoues, griep en sinusitis te hanteer vir beter algemene gesondheid. As gevolg van die aktiewe bestanddele word Sinulex® Forte Stroop slegs aangedui vir terapeutiese gebruik vanaf die ouderdom van 2 jaar en ouer. Hierdie aktiewe bestanddele is nuttig vir simptome van verligting van sinusdruk, sinusopeenhoping, post-nasale drup, verkoues en griepsimptome, deur die respiratoriese en immuunstelsels te ondersteun. Die aktiewe bestanddele kan ook die immuunfunksie ondersteun van diene wat asimptomaties is as 'n laerisiko-gesondheidsaanvulling. Dit is 'n gesondheidsaanvulling wat belangrike ekspektorerende, anti-bakteriese, anti-mikrobiële, anti-

inflammatoriese en kalmerende eienskappe bevat en kan gebruik word om die respiratoriese kanaal te ondersteun, wat die paranasale sinusse ondersteun. Sinulex® Forte Stroop word aangedui vir selfadministrasie as 'n laerisiko-gesondheidsaanvulling, hoewel slegs 'n gesondheidsorgverskaffer dit kan aandui as 'n byvoeglike behandeling vir 'n bestaande behandelingsregime vir individuele persone. Dit word nie aangedui as 'n alternatiewe terapie om konvensionele medisyne of enige ander behandelings wat deur 'n gesondheidsorgverskaffer voorgeskryf word, te vervang nie. Sinulex® Forte Stroop is 'n medisinale gesondheidsaanvulling wat nie bedoel is (of aangedui word) nie vir instandhouding of alternatiewe onderhoudsterapie, maar eerder vir simptome verligting wanneer hierdie medisyne nodig is. Dit word nie aangedui as 'n geneesmiddel of monoterapie vir ernstige toestande nie omdat Sinulex® Forte Stroop nie bedoel (of aangedui) is om siektes te diagnoseer, te behandel, te voorkom of te genees nie. Dit word streng aangedui vir simptome verligting as 'n laerisiko ondersteunende aanvulling.

8. Wat jy moet weet voordat jy Sinulex® Forte Stroop gebruik.**Moenie Sinulex® Forte Stroop neem nie:**

- as jy hipersensitief (allergies) is vir die aktiewe bestanddele, of enige van die ander bestanddele Sinulex® Forte Stroop (gelys in afdeling 6).
- as jy op hipoglisemiese medikasie is, aangesien hierdie medisyne ook hipoglisemiese eienskappe bevat (sien 'Waarskuwings en voorsorgmaatreëls').
- as u 'n operasie of tandheelkundige prosedure geskeduleer het, vir ten minste twee weke voor dit.
- sonder om u gesondheidsorgverskaffer te raadpleeg as u 'n bestaande behandelingsregime het.

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet geneem word met Sinulex® Forte Stroop:

- as jy reeds op hipoglisemiese medikasie is as gevolg van die hipoglisemiese verwante eienskappe wat reeds in hierdie medisyne voorkom.
- as jy diabetes het.
- wanneer jy swanger is of borsvoed omdat veiligheid tydens swangerskap en laktasie nie vasgestel is nie.

Kinders

Moenie Sinulex® Forte Stroop aan kinders wat onder die ouderdom van 2 jaar gee nie, want dit is onwaarskynlik dat dit veilig sal wees. Moenie probeer om hierdie medisyne te rekonstrueer nie. Die aanbevole dosisse word spesifiek bereken om slegs veilig te wees vir persone bo die ouderdom van 2 jaar. Hou buite bereik van kinders.

Ander medisyne en Sinulex® Forte Stroop

Sê altyd vir jou gesondheidsorgverskaffer as jy enige ander medisyne neem. Anders kan die gevolge van Sinulex® Forte Stroop asook ander medisyne inmengende of versterkte effekte hê.

Sinulex® Forte Stroop met alkohol

Ons beveel nie aan dat u Sinulex® Forte Stroop met alkohol gebruik nie, aangesien dit slegs die voordele wat uit die aktiewe bestanddele verkry kan word, verder kan benadeel.

Swangerskap en borsvoeding

Veiligheid vir gebruik tydens swangerskap en borsvoeding is nie vasgestel nie. As u swanger is of borsvoed, dink dat u swanger is of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.

Bestuur en gebruik van masjiene

Geen ongewenste effekte op die bestuur en gebruik van masjiene is aangemeld met Sinulex® Forte Stroop nie. Dit is nie altyd moontlik om te voorspel in watter mate 'n medisyne die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet verseker dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle bewus is van die mate tot wat 'n medisyne hulle beïnvloed nie.

Sinulex® Forte Stroop bevat die volgende eksipiënte:

- Sorbitol 2828 mg
- Ander onaktiewe bestanddele:
 - Sitroensuur
 - Karmellose natrium
 - Tutti frutti geur (CR-048)
 - Gliserien
 - Kaliumsorbitaat
 - Natriumbenzoaat

- o Waterstofdioksied

9. Hoe om Sinulex® Forte Stroop te gebruik.

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Neem altyd Sinulex® Forte Stroop presies soos beskryf in hierdie pamflet of soos jou dokter, apteker of verpleegster jou vertel het. Raadpleeg u dokter, apteker of verpleegster as u nie seker is nie.

- Die gewone dosis is 1½ teelepel of 7 mL stroop, 3 keer per dag, wat die daaglikse ekwivalent van 3 keer 'n volle enkele dosis is, vir **adolessente ouer as 12, volwassenes en bejaardes**; en is die maksimum aanbevole daaglikse en/of totale dosis.
- Die gewone dosis is ¾ teelepel of 3,5 mL stroop, 3 keer per dag, wat die daaglikse ekwivalent van 1,5 keer 'n volle enkele dosis is, vir **kinders bo die ouderdom van 6 jaar**; en is die maksimum aanbevole daaglikse en/of totale dosis.
- Die gewone dosis is ½ teelepel of 2.1 mL van stroop, 3 keer per dag, wat die daaglikse ekwivalent van 1 volle enkeldosis is, vir **kinders bo die ouderdom van 2 jaar**; en is die maksimum aanbevole daaglikse en/of totale dosis.
- Gebruik 'n meetlepel of die meetbeker wat voorsien word om veilige inname/sluk van die medisyne te verseker.
- Neem slegs hierdie produk mondelings.

As jy meer Sinulex® Forte Stroop neem as wat jy moet

- jy kan gastro-intestinale ongemak ervaar.
- In die geval van oordosering, raadpleeg u dokter of apteker. Indien een nie beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As jy vergeet om Sinulex® Forte Stroop te gebruik

- moet dan nie die maksimum aanbevole daaglikse en/of totale dosis oorskry nie; en
- moenie 'n dubbele dosis gebruik om op te maak vir vergete individuele dosisse nie.

10. Moontlike nuwe-effekte.

Sinulex® Forte Stroop Kan nuwe-effekte hê. Nie alle nuwe-effekte wat vir Sinulex® Forte Stroop gerapporteer word, word in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid vererger of as jy enige nadelige gevolge ervaar terwyl jy Sinulex® Forte Stroop neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies. As enige van die volgende gebeur, hou op om Sinulex® Forte Stroop te neem/gebruik en vertel u dokter onmiddellik of gaan na die ongevalle-afdeling by u naaste hospitaal:

- 'swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal',
- 'uitslag of jeuk',
- 'floute'

Dit is alles baie ernstige nuwe-effekte en kan tekens wees van 'n allergiese reaksie of hipersensitiwiteit vir Sinulex® Forte Stroop. Miskien het u dringende mediese hulp of hospitalisasie nodig. As u enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, moet u jou dokter of apteker in kennis stel.

Verslagdoening van nuwe-effekte

As u nuwe-effekte kry, praat dan met u dokter, apteker of verpleegster. U kan ook nuwe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn onder SAHPRA se publikasies gevind word: <https://www.sahpra.org.za/Publications/Index/8>. Deur verslagdoening van nuwe-effekte, kan jy help om meer inligting oor die veiligheid van Sinulex® Forte Stroop.

11. Hoe om Sinulex® Forte Stroop te stoor.

Stoor alle medisyne buite bereik van kinders. Stoor in 'n koel, droë plek by temperatuur van 59-77° F, gelykstaande aan 15-25° C, en met omgewingsvogtigheid tussen 35% en 65%. Moenie verkoel of vries nie. Stoor in die oorspronklike pakket of houer. Beskerm teen direkte sonlig en vog. Moenie dit gebruik na die vervaldatum wat op die etiket aangedui is nie. Moenie Sinulex® Forte Stroop gebruik as jy 'n abnormale voorkoms of onaangename reuk opmerk nie, aangesien die produk moontlik verval het of onbehoorlik gestoor was. Gee alle ongebruikte medisyne aan u apteker terug.

Moenie ontslae raak van ongebruikte medisyne in dreine of rioolstelsels nie.

Herwin asseblief die leë houers.

12. Inhoud van die pak en ander inligting.

Wat Sinulex® Forte Stroop bevat

Die aktiewe bestanddele is soos gelys aan die begin van hierdie pamflet. Die ander bestanddele word gelys as eksipiënte (sien afdeling 2) in hierdie pamflet.

Hoe Sinulex® Forte Stroop lyk en inhoud van die pak

Sinulex® Forte Stroop kom in pet-verseëelde bottels van 100 mL stroop per bottel. Die aktiewe bestanddele bied 'n totaal van 858 mg per 7 mL stroop. Sinulex® Forte Stroop het 'n 7 mL stroop dosis vorm met 'n spesifieke voorkoms: Vloeistof, stroop, ondeursigtige esdoring kleur, gietbare viskositeit, merke nie van toepassing nie. Die karton dien as die sekondêre verpakking vir berging, wat ook die regte etikettering toon.

Houer van Registrasiesertifikaat

Tara Pharmaceuticals (Pty) Ltd
36 Sovereign Drive, Route 21 Corporate Park, Irene, Gauteng, 0062, South Africa

Aansoeknommer

DCFS-db4f9a
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