



SCHEDULING STATUS: [S0]

PROPRIETARY NAME AND DOSAGE FORM
Sinulex Forte Syrup

COMPOSITION

ACTIVE INGREDIENTS: (Quantity per 7 ml)
Primula veris L. (Primula veris flower) 198 mg
Rumex acetosa L. (Field sorrel herb) 198 mg
Sambucus nigra L. (Elder flower) 198 mg
Verbena officinalis L. (Verbena herb) 198 mg
Gentiana lutea L. (Yellow gentian root) 66 mg
Total of Active Substances per 7 ml = 858 mg

INACTIVE INGREDIENTS:

Citric Acid, Flavouring (Cherry), Water
Contains Sorbitol (2,8 mg / 7 ml)
Preservatives: Potassium sorbate (0,035 % *m/v*); Sodium benzoate (0,045 % *m/v*)
Contains Ethanol 6,03 % (*m/m*)

CATEGORY AND CLASS

D.5.8 Preparations for the common cold including nasal decongestants. Complimentary medicine: Western Herbal

PHARMACOLOGICAL ACTION:
PHARMACODYNAMIC PROPERTIES

Sinulex Forte Syrup is a combination of Primula Veris Flower, Field Sorrel Herb, Elder Flower, Verbena Herb and Yellow Gentian Root.
Active ingredients are used for the symptomatic relief of inflammation of the paranasal sinuses.

PHARMACOKINETIC PROPERTIES

The active ingredients are well known. Pharmacokinetic studies have not been conducted on **Sinulex Forte Syrup**.

INDICATIONS

To reduce symptoms brought on by acute inflammation of the paranasal sinuses.

CONTRAINDICATIONS

- Hypersensitivity to the active ingredients or any excipients contained within Sinulex Forte Syrup.
- Pregnant or breastfeeding women.
- Children under 2 years of age.

WARNINGS AND SPECIAL PRECAUTIONS

Sinulex Forte Syrup does not intend to prevent or cure any form of illness or disease and should not replace any medication. If you suffer from any chronic medical conditions, consult your healthcare practitioner before using this product. Do not exceed the daily dose.
- Contains Sorbitol and may have a laxative effect. Patients with the rare hereditary condition of Sorbitol Intolerance should not take **Sinulex Forte Syrup**.
- Stop using **Sinulex Forte Syrup** at least 2 weeks before a scheduled surgery.

EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINERY

No studies have been performed regarding the effect of **Sinulex Forte Syrup** on the ability to drive or operate machinery. It is unlikely that **Sinulex Forte Syrup** would affect the ability to drive or operate machinery.

INTERACTIONS

Adverse effects have not become known with the simultaneous ingestion of **Sinulex Forte Syrup** with food and drink.
There are no known interactions with other medicinal products to date.
- Concomitant use of *Gentiana lutea* L. (Yellow gentian root) might lower pressure or interfere with drug treatment to decrease blood pressure.
- Concomitant use of *Gentiana lutea* L. (Yellow gentian root) along with medications for high blood pressure might cause your blood pressure to go too low.
- Don't use *Rumex acetosa* L. (Field sorrel herb) without professional's advice if you have ever had or are at risk of getting kidney stones.
- Concomitant use of *Sambucus nigra* L. (Elder flower) along with diabetes medications might cause your blood sugar to be too low.

HUMAN PRODUCTION:

PREGNANCY AND LACTATION

Not recommended for use during pregnancy and lactation, as safety and efficacy of Sinulex Forte Syrup have not been established (see "WARNINGS AND SPECIAL PRECAUTIONS")
Consult a healthcare professional for further information.

DOSAGE AND DIRECTIONS FOR USE

Unless prescribed differently, **Sinulex Forte Syrup** is only to be taken three times daily, as indicated in the table below, and by using the measuring cup.

AGE	SINGLE DOSE	TOTAL DAILY DOSE
Children under the age of 2 years	Not Recommended	Not Recommended
Children aged 2 to 5	2,1 ml = 2,5 mg	6,3 ml = 7,5 mg (3 x 2,1ml)
Children aged 6 to 11	3,5 ml = 4,2 mg	10,5 ml = 12,6 mg (3 x 3,5ml)
Adults and adolescents from the age of 12	7,0 ml = 8,4 mg	21,0 ml = 25,2 mg (3 x 7,0ml)

Patients with gastrointestinal sensitivity to take **Sinulex Forte Syrup** after meals.
SHAKE THE BOTTLE WELL BEFORE USE.
Unless prescribed differently, **Sinulex Forte Syrup** may be taken for 7-14 days. If the symptoms worsen or persist, please consult your healthcare professional.

SIDE EFFECTS

There are no known side effects with **Sinulex Forte Syrup**.
Gastrointestinal disorders:
Stomach ache, nausea, and severe laxative effects (*less frequent*).
Skin and subcutaneous tissue disorders:
Skin rash, reddening of the skin, itching, angioedema, shortness of breath, facial swelling (*less frequent*).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Treatment of overdosage is supportive and symptomatic.

IDENTIFICATION

Sinulex Forte Syrup is a light-brown, viscous, and translucent syrup with a cherry flavour. Slight opaque or the appearance of trace amounts of fragments may occur during the storage phase, which has no impact of the quality or the effectiveness of the product, and happens because of normal change related to the composition of the product's all-natural, plant-based ingredients.

PRESENTATION

Sinulex Forte Syrup is available in 100 ml brown color plastic bottle with white cap.

STORAGE INSTRUCTIONS

Keep in a dry, cool place at or below 25°C.
Do not use after expiry date.
Protect from light.
Keep the bottle tightly closed.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

Will be allocated on registration

Sinulex Forte Syrup is an unregistered medicine and has not been evaluated by SAHPRA for its quality, safety or intended use.

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

28 November 2019

PATIENT INFORMATION LEAFLET

D.5.8 Preparations for the common cold including nasal decongestants. Complimentary medicine: Western Herbal

SCHEDULING STATUS: [S0]

PROPRIETARY NAME AND DOSAGE FORM
Sinulex Forte Syrup

Read all of this leaflet carefully because it contains important information for you.
Sinulex Forte Syrup is available without a doctor's prescription. However, 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 pharmacist if you need more information or advice.
You must see a doctor if your symptoms worsen or do not improve.

WHAT SINULEX FORTE SYRUP CONTAINS:

ACTIVE INGREDIENTS: (Quantity per 7 ml)
Primula veris L. (Primula veris flower) 198 mg
Rumex acetosa L. (Field sorrel herb) 198 mg
Sambucus nigra L. (Elder flower) 198 mg
Verbena officinalis L. (Verbena herb) 198 mg
Gentiana lutea L. (Yellow gentian root) 66 mg
Total of Active Substances per 7 ml = 858 mg

INACTIVE INGREDIENTS:

Citric Acid, Flavouring (Cherry), Water
Contains Sorbitol (2,8 mg / 7 ml)
Preservatives: Potassium Sorbate (0,035 % *m/v*); Sodium Benzoate (0,045 % *m/v*)
Contains Ethanol 6,03 % (*m/m*)

WHAT SINULEX FORTE SYRUP IS AND WHAT IT IS USED FOR:

Sinulex Forte Syrup contains Yellow Gentian Root, Primula Veris Flower, Field Sorrel Herb, Elder Flower and Verbena Herb to help relieve colds, flu, postnasal drip, and sinusitis symptoms.
The active ingredients in **Sinulex Forte Syrup** 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.

BEFORE YOU TAKE SINULEX FORTE SYRUP:

- Do not take **Sinulex Forte Syrup** if:
- you are allergic (hypersensitive) to any of the ingredients in **Sinulex Forte Syrup**.
 - you are under 2 years of age.
 - pregnant/breastfeeding your baby.

TAKE SPECIAL CARE WITH SINULEX FORTE SYRUP:

Sinulex Forte Syrup contains sorbitol and may have a laxative reaction. If you have been told that you have an intolerance to some sugars, you should not take **Sinulex Forte Syrup**.
Patients with a tendency to kidney stones should consult their doctor before taking **Sinulex Forte Syrup**.
Stop using **Sinulex Forte Syrup** at least 2 weeks before surgery.

PLEASE CONSULT YOUR DOCTOR IF YOU ARE:

PREGNANT AND BREASTFEEDING:
Do not use **Sinulex Forte Syrup** during pregnancy or while you are breastfeeding, as safety and efficacy have not been established. If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare professional before taking this medicine.

DRIVING AND USING MACHINERY:

No studies have been performed regarding the effect of **Sinulex Forte Syrup** on the ability to drive or operate machinery. It is unlikely that **Sinulex Forte Syrup** would affect the ability to drive or operate machinery.

TAKING SINULEX FORTE SYRUP WITH FOOD AND DRINK:

There are no known side effects to taking **Sinulex Forte Syrup** with food and drink.

TAKING OTHER MEDICINES WITH SINULEX FORTE SYRUP:

Always tell your healthcare professional if you are taking other medicines on a regular basis, including complementary or traditional medicines. The use of **Sinulex Forte Syrup** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.
Consult your doctor if you want to take **Sinulex Forte Syrup** in combination with other medicines or treatments such as:
- Antidiabetics as concomitant use.
- Anti-Hypertensive drugs as concomitant use.
- Blood thinners as concomitant use.
- Kidney stones risk.

HOW TO TAKE SINULEX FORTE SYRUP:

Unless prescribed differently, **Sinulex Forte Syrup** is only to be taken three times daily, as indicated in the table below, and by using the measuring cup.

AGE	SINGLE DOSE	TOTAL DAILY DOSE
Children under the age of 2 years	Not Recommended	Not Recommended
Children aged 2 to 5	2,1 ml = 2,5 mg	6,3 ml = 7,5 mg (3 x 2,1ml)
Children aged 6 to 11	3,5 ml = 4,2 mg	10,5 ml = 12,6 mg (3 x 3,5ml)
Adults and adolescents from the age of 12	7,0 ml = 8,4 mg	21,0 ml = 25,2 mg (3 x 7,0ml)

Sinulex Forte Syrup is taken 3 x daily, morning, midday, and evening, either undiluted or mixed with some water. Do not swallow with alcohol.
Only drink with a glass of water if necessary. **Sinulex Forte Syrup** can also be taken before, during, or after meals. However, we advise patients with gastrointestinal sensitivity to take **Sinulex Forte Syrup** after meals, instead of before or during.
Shake well before use.
Do not exceed the recommended daily dosage.
If the condition does not improve or gets worse, talk to your doctor, healthcare professional or pharmacist.

IF YOU TAKE MORE SINULEX FORTE SYRUP THAN YOU SHOULD:

Treatment of overdosage is supportive and symptomatic.

IF YOU FORGET TO TAKE SINULEX FORTE SYRUP:

Always take **Sinulex Forte Syrup** as prescribed. If you miss a dose just continue the schedule as prescribed and not take extra.

POSSIBLE SIDE EFFECTS:

There are no known side effects with **Sinulex Forte Syrup**.
Gastrointestinal disorders:
Stomach ache, nausea, and severe laxative effects (*less frequent*).
Skin and subcutaneous tissue disorders:
Skin rash, reddening of the skin, itching, angioedema, shortness of breath, facial swelling (*less frequent*).

STORING AND DISPOSING OF SINULEX FORTE SYRUP:

Store at or below 25 ° C in a dry place to protect from moisture build-up and condensation. **Keep out of reach of children.** Do not use after the expiry date. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems.

PRESENTATION OF SINULEX FORTE SYRUP:

Sinulex Forte Syrup is available in 100 ml brown color plastic bottle with white cap.

IDENTIFICATION OF SINULEX FORTE SYRUP:

Sinulex Forte Syrup is a light-brown, viscous, and translucent syrup with a cherry flavour.

REGISTRATION NUMBER:

Will be allocated on registration

NAME OF APPLICANT:

Tara Pharmaceuticals
Unit 9, Fish Eagle Park
Old Paardevlei road
Somerset West
7130
Helpdesk: 086 111 8272

DATE OF PUBLICATION OF THIS LEAFLET:

28 November 2019

Sinulex Forte Syrup is an unregistered medicine and has not been evaluated by SAHPRA for its quality, safety or intended use.



SKEDULERINGSTATUS: [S0]

EIENDOMSNAAM EN DOSERINGSVORM
Sinulex Forte Stroop

SAMESTELLING

AKTIEWE BESTANDDELE: (Hoeveelheid per 7 ml)

<i>Primula veris</i> L. (Primula veris blom)	198 mg
<i>Rumex acetosa</i> L. (Veldbos)	198 mg
<i>Sambucus nigra</i> L. (Vlier)	198 mg
<i>Verbena officinalis</i> L. (Verbana krui)	198 mg
<i>Gentiana lutea</i> L. (Geel gentiaanse wortel)	66 mg

Totaal aktiewe bestanddele per 7 ml = 858 mg

ONAKTIEWE BESTANDDELE:

Sitroensuur, geurmiddel (kersie), water

Bevat Sorbitol (2,8 mg / 7 ml)

Preserveermiddels: Kaliumsorbaat (0,035 % *m/v*); Natriumbenzoaat (0,045 % *m/v*)

Bevat etanol 6,03 % (*m/m*)

KATEGORIE EN KLAS

D.5.8 Voorbereidings vir gewone verkoue, insluitend nasale dekongestante.

Komplimentêre medisyne: Westerse Kruie

FARMAKOLOGIESE AKSIE:

FARMAKODINAMIESE EIENSKAPPE

Sinulex Forte Stroop is 'n kombinasie van Primula Veris Blom, Veldbos, Vlier, Verbana krui en Geel Gentiaanse Wortel.

Hierdie bestanddele dien as geneesmiddel vir die simptome van verligting van paranasal inflammasie.

FARMAKOKINETIESE EIENSKAPPE

Die aktiewe bestanddele is goed bekend. Farmakokinetiese studies is nie op **Sinulex Forte Stroop** uitgevoer nie.

INDIKASIES

Om simptome te beveg weens akute ontsteking van die paranasale sinusse.

KONTRA-INDIKASIES

- Hipersensitiwiteit vir die aktiewe bestanddele of enige ander bestanddele in **Sinulex Forte Stroop**.

- Swanger is of jou baba borsvoed.

- Kinders onder 2 jaar oud.

WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS

Bevat Sorbitol en kan 'n lakserende effek hê. Pasiënte met 'n seldsame oorerlike Sorbitol intoleransie moet nie **Sinulex Forte Stroop** neem nie. Pasiënte met 'n neiging tot nierstene moet hulle dokter raadpleeg voordat hulle **Sinulex Forte Stroop** neem. Stop inname van **Sinulex Forte Stroop** ten minste 2 weke voor u 'n operasie kry.

BESTUUR EN GEBRUIK VAN MASJINERIE:

Geen studies is gedoen met betrekking tot die effek van **Sinulex Forte Stroop** op die vermoë om masjinerie te bestuur of te bestuur nie. Dit is onwaarskynlik dat **Sinulex Forte Stroop** die vermoë om masjinerie te bestuur of te bestuur beïnvloed.

INTERAKSIES

Daar is geen bekende nuwe-effekte met die gelyktydige inname van Sinulex Forte Stroop saam met kos en drinkgoed nie.

Daar is tot dusver geen interaksies met ander medisyne bekend nie.

- Gelyktydige gebruik van *Gentiana lutea* L. (Geel gentiaanse wortel) mag dalk bloeddruk verlaag of teen die medikasie werk om bloeddruk te behandel .

- Gelyktydige gebruik van *Gentiana lutea* L. (Geel gentiaanse wortel) saam met medikasie teen hoë bloeddruk kan veroorsaak dat u bloeddruk te laag word.

- Moenie *Rumex acetosa* L. (Veldbos) gebruik sonder die advies van 'n dokter nie, as u ooit nierstene opgedoen het of die risiko loop om dit te kry.

- Gelyktydige gebruik van *Sambucus nigra* L. (Vlier) saam met medikasie vir diabetes kan veroorsaak dat u bloedsuiker te laag word.

Menslike produksie:

SWANGERSKAP EN LAKTASIE

Word nie aanbeveel vir gebruik tydens swangerskap en laktasie nie, aangesien die veiligheid en effektiwiteit van **Sinulex Forte Stroop** nog nie vasgestel is nie (sien "WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS") Raadpleeg 'n gesondheidswerker vir verdere inligting.

DOSIS EN GEBRUIKSAANWYSINGS

Tensy anders voorgeskryf, moet **Sinulex Forte Stroop** slegs drie keer per dag geneem word, wat volgens die onderstaande tabel aangedui word, en met behulp van die maatbeker.

OUDERDOM	ENKEL DOSIS	TOTALE DAAGLIKSE DOSIS
Kinders jonger as 2 jaar	Nie aanbeveel	Nie aanbeveel
Kinders van 2 tot 5 jaar	2,1 ml = 2,5 mg	6,3 ml = 7,5 mg (3 x 2,1ml)
Kinders van 6 tot 11 jaar	3,5 ml = 4,2 mg	10,5 ml = 12,6 mg (3 x 3,5ml)
Volwassenes en adolessente vanaf 12	7,0 ml = 8,4 mg	21,0 ml = 25,2 mg (3 x 7,0ml)

Pasiënte met 'n sensitiewe spysverteringskanaal moet **Sinulex Forte Stroop** na maaltye neem.

SKUD DIE BOTTEL GOED VOOR GEBRUIK.

Sinulex Forte Stroop mag 7-14 dae geneem word, tensy anders voorgeskryf. Raadpleeg u gesondheidsorg werker as die simptome vererger of voortduur.

NEWE-EFFEKTE

Daar is geen bekende nuwe-effekte met **Sinulex Forte Stroop** nie.

Gastrointestinale klages:

Maagpyn, naarheid en ernstige lakseermiddels (*minder gereeld*).

Vel en onderhuidse weefsel klages:

veluitslag, rooiheid van die vel, jeuk, angio-edeem, kortasem, swelling in die gesig (*minder gereeld*).

BEKENDE SIMPTOME VAN OORDOSERING EN DIE BEHANDELING DAARVAN

Behandeling van oordosering is ondersteunend en simptome.

IDENTIFIKASIE

Sinulex Forte Stroop is 'n ligbruin, viskose en deurskynende stroop met 'n kersie smaak. Wolkerige voorkoms weens kruie fragmente kan voorkom tydens die storsingsfase, alhoewel dit geen impak op die kwaliteit of die doeltreffendheid van Sinulex Forte Stroop het nie.

AANBIEDING

Sinulex Forte Stroop is beskikbaar in 100 ml bruin kleurige plastiekbottel met wit doppie.

BERGINGSAAANWYSINGS

Hou op 'n droë, koel plek by of onder 25 ° C.

Moet nie na die vervaldatum gebruik nie.

Beskerm teen lig.

Hou die bottel dig toe.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER

Sal toegeken word met registrasie

Sinulex Forte Stroop is 'n ongeregisteerde medisyne en is nie deur SAHPRA geëvalueer vir die gehalte, veiligheid of beoogde gebruik nie.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

Tara Pharmaceuticals (Pty) Ltd

Eenheid 9, Fish Eagle Park

Ou Paardevlei Road

Somerset-Wes

7130

Suid-Afrika

DATUM VAN PUBLIKASIE

28 November 2019

PASIËNTINLIGTINGSBLAD

D.5.8 Voorbereidings vir gewone verkoue, insluitend nasale dekongestante.

Komplimentêre medisyne: Westerse Kruie

SKEDULERINGSTATUS: [S0]

EIENDOMSNAAM EN DOSERINGSVORM
Sinulex Forte Stroop

Lees die hele pamflet sorgvuldig, want dit bevat belangrike inligting vir u. **Sinulex Forte Stroop** is beskikbaar sonder 'n voorskrif van 'n dokter. U moet egter steeds **Sinulex Forte Stroop** versigtig gebruik om die beste resultate daarmee te kry. Bewaar hierdie pamflet. Miskien moet u dit weer lees. Moenie **Sinulex Forte Stroop** met enige ander persoon deel nie. Vra u apteker as u meer inligting of advies benodig. U moet 'n dokter sien as u simptome vererger of nie verbeter nie.

WAT SINULEX FORTE STROOP BEVAT:

AKTIEWE BESTANDDELE: (Hoeveelheid per 7 ml)

<i>Primula veris</i> L. (Primula veris blom)	198 mg
<i>Rumex acetosa</i> L. (Veldbos)	198 mg
<i>Sambucus nigra</i> L. (Vlier)	198 mg
<i>Verbena officinalis</i> L. (Verbana krui)	198 mg
<i>Gentiana lutea</i> L. (Geel gentiaanse wortel)	66 mg

Totaal aktiewe bestanddele per 7 ml = 858 mg

ONAKTIEWE BESTANDDELE:

Sitroensuur, geurmiddel (kersie), water

Bevat Sorbitol (2,8 mg / 7 ml)

Preserveermiddels: Kaliumsorbaat (0,035 % *m/v*); Natriumbenzoaat (0,045 % *m/v*)

Bevat etanol 6,03 % (*m/m*)

WAT IS SINULEX FORTE STROOP EN WAARVOOR WORD DIT GEBRUIK:

Sinulex Forte Stroop bevat geel-gentiaanse wortel, Primula Veris-blom, veldbos, Vlier, Verbana krui om simptome van verkoue, griep, postnasale drup en sinusitis te verlig. Die aktiewe bestanddele in **Sinulex Forte Stroop** het sterk anti-inflammatoriese, antivirale, antibakteriese en antifungale eienskappe wat kan help om inflammasie te verminder asook bakterieë en virusse wat respiratoriese infeksies en ophoping veroorsaak, te beveg.

VOORDAT U SINULEX FORTE STROOP NEEM:

MOENIE SINULEX FORTE STROOP NEEM AS:

- u allergies (hipersensitief) is vir enige van die bestanddele in **Sinulex Forte Stroop**.

- u swanger is of u baba borsvoed.

- u jonger as 2 jaar os.

NEEM SPESIALE SORG MET SINULEX FORTE STROOP:

Sinulex Forte Stroop beoog nie om enige vorm van siekte of siektes te voorkom of te genees nie en moet ook nie medikasie vervang nie. As u aan chroniese mediese toestande ly, raadpleeg u geneesheer voordat u hierdie produk gebruik. Moenie die daaglikse dosis oorskry nie. **Sinulex Forte Stroop** bevat Sorbitol wat 'n lakserende effek kan hê. As daar aan u gesê was dat u 'n intoleransie vir suiker het, moet u nie **Sinulex Forte Stroop** neem nie. Pasiënte met 'n neiging tot nierstene moet hulle dokter raadpleeg voordat hulle **Sinulex Forte Stroop** neem.

RAADPLEEG ASSEBLIEF U DOKTER OF APTEKER VOOR GEBRUIK INDIEN U: SWANGERSKAP EN BORSVOEDING:

Moenie **Sinulex Forte Stroop** gebruik tydens swangerskap of terwyl u baba borsvoed nie, aangesien veiligheid en effektiwiteit nie vasgestel is nie. As u swanger is of u baba borsvoed, raadpleeg u dokter, apteker of ander gesondheidsorgwerker voordat u hierdie medisyne gebruik.

NEEM SINULEX FORTE STROOP SAAM MET KOS EN DRANK:

Daar is geen bekende nuwe-effekte indien **Sinulex Forte Stroop** saam met kos en drinkgoed geneem word nie.

BESTUUR EN GEBRUIK VAN MASJINERIE:

Geen studies is gedoen met betrekking tot die effek van **Sinulex Forte Stroop** op die vermoë om masjinerie te bestuur of te bestuur nie. Dit is onwaarskynlik dat **Sinulex Forte Stroop** die vermoë om masjinerie te bestuur of te bestuur beïnvloed.

DIE NEEM VAN ANDER MEDISYNE SAAM MET SINULEX FORTE STROOP:

Vertel altyd u gesondheidswerker of u gereeld medisyne neem, insluitend aanvullende of tradisionele medisyne. Die gebruik van **Sinulex Forte Stroop** saam met hierdie medisyne kan ongewenste interaksies veroorsaak. Raadpleeg u dokter, apteker of ander gesondheidsorgwerker vir advies.

Raadpleeg u dokter as u **Sinulex Forte Stroop** wil neem in kombinasie met ander medisyne of behandelings soos:

- Antidiabetika as gelyktydig gebruik.

- Anti-hipertensiewe medisyne as gelyktydige gebruik.

- Bloedverdunner as gelyktydig gebruik.

- Risiko vir nierstene.

HOE OM SINULEX FORTE STROOP TE NEEM:

Tensy anders voorgeskryf, moet **Sinulex Forte Stroop** slegs drie keer per dag geneem word, met die dosis volgens die ouderdomshakies wat in die onderstaande tabel aangedui word, en met behulp van die maatbeker.

OUDERDOM	ENKEL DOSIS	TOTALE DAAGLIKSE DOSIS
Kinders jonger as 2 jaar	Nie aanbeveel	Nie aanbeveel
Kinders van 2 tot 5 jaar	2,1 ml = 2,5 mg	6,3 ml = 7,5 mg (3 x 2,1ml)
Kinders van 6 tot 11 jaar	3,5 ml = 4,2 mg	10,5 ml = 12,6 mg (3 x 3,5ml)
Volwassenes en adolessente vanaf 12	7,0 ml = 8,4 mg	21,0 ml = 25,2 mg (3 x 7,0ml)

Sinulex Forte Stroop word 3 x daaglikse geneem, een keer in die oggend, een keer gedurende die middag, en een keer in die aand, of onverdund of met water gemeng. Moenie met alkohol sluk nie.

Drink slegs met 'n glas water indien nodig. **Sinulex Forte Stroop** kan ook voor, tydens of na etes geneem word. Ons beveel egter pasiënte met gastro-intestinale sensitiviteit aan om **Sinulex Forte Stroop** na maaltye te neem, in plaas van voor of tydens.

Skud goed voor gebruik.

Moet nie die aanbevole daaglikse dosis oorskry nie.

As die toestand nie verbeter en erger word, moet u dit met u dokter, gesondheidswerker of apteker bespreek.

AS U MEER SINULEX FORTE STROOP NEEM AS WAT U BEHOORT:

Behandeling van oordosering is ondersteunend en simptome.

AS U VERGEET OM SINULEX FORTE STROOP TE NEEM:

Neem **Sinulex Forte Stroop** altyd soos voorgeskryf. As u 'n dosis mis, gaan voort met die skedule soos voorgeskryf en moenie ekstra neem nie.

MOONTLIKE NEWE-EFFEKTE:

Daar is geen bekende nuwe-effekte met **Sinulex Forte Stroop** nie.

Gastrointestinale klages:

Maagpyn, naarheid en ernstige lakseermiddels (*minder gereeld*).

Vel en onderhuidse weefsel klages:

veluitslag, rooiheid van die vel, jeuk, angio-edeem, kortasem, swelling in die gesig (*minder gereeld*).

BERGING EN WEGDOEN VAN SINULEX FORTE STROOP:

Bêre by of benede 25 °C op 'n droë plek om te beskerm teen vogtigheid en condensasie.

Hou buite bereik van kinders. Moet nie na die vervaldatum gebruik nie. Besorg alle ongebruikte medisyne terug aan u apteker. Moenie ongebruikte medisyne in dreine of rioolstelsels wegdoen nie.

AANBIEDING VAN SINULEX FORTE STROOP:

Sinulex Forte Stroop is beskikbaar in 100 ml bruin kleurige plastiekbottel met wit doppie.

IDENTIFISERING VAN SINULEX FORTE STROOP:

Sinulex Forte Stroop is 'n ligbruin, viskose en deurskynende stroop met 'n kersie-smaak.

REGISTRASIENOMMER:

Sal toegeken word met registrasie

NAAM VAN APPLIKANT:

Tara Pharmaceuticals

Eenheid 9, Fish Eagle Park

Ou Paardevlei-pad

Somerset-Wes

7130

Hulptoonbank: 086 111 8272

DATUM VAN PUBLIKASIE VAN HIERDIE PAMFLET:

28 November 2019

Sinulex Forte Stroop is 'n ongeregisteerde medisyne en is nie deur SAHPRA geëvalueer vir die gehalte, veiligheid of beoogde gebruik nie.