



English

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:**

S0

Sinulex® Forte Fizzy Tablets**Strength**

493.71 mg per tablet

Pharmaceutical form

Tablet, effervescent, dissolvable oral

Active substances

| | |
|------------------------|---------|
| Vitamin C | 300 mg |
| Echinacea flower | 125 mg |
| Horseradish | 50 mg |
| Zinc gluconate | 16.7 mg |
| Vitamin B2 | 2 mg |
| Vitamin D3 | 8.33 µg |

Contains sugar and sweetener:

- Isomalt 140 mg
- Sucralose / Acesulfame K..... 10 mg

This product is 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 Fizzy Tablets 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 Fizzy Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Sinulex® Forte Fizzy Tablets 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 Fizzy Tablets is and what it is used for.
2. What you need to know before you use Sinulex® Forte Fizzy Tablets.
3. How to take Sinulex® Forte Fizzy Tablets.
4. Possible side effects.
5. How to store Sinulex® Forte Fizzy Tablets.
6. Contents of the pack and other information.

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

Sinulex® Forte Fizzy Tablets support the immune system to deal with allergens, colds, flu, and sinusitis for better overall health. Due to the active substances, Sinulex® Forte Fizzy Tablets are indicated for therapeutic use only from the age of 6 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 and can be used to maintain healthy levels of Vitamin B2, Vitamin C, Vitamin D3, and Zinc. It is a health supplement that contains important immunomodulator and immunostimulant properties and can be

used to support the respiratory tract, supporting the paranasal sinuses. Sinulex® Forte Fizzy Tablets are 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. When using Sinulex® Forte Fizzy Tablets for maintenance therapy, it is specifically indicated for the purposes of maintaining healthy levels of its key ingredients and is not indicated for alternative maintenance therapy. It is not indicated as a cure-all or monotherapy for serious conditions because Sinulex® Forte Fizzy Tablets are 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 Fizzy Tablets.**Do not take Sinulex® Forte Fizzy Tablets:**

- if you are hypersensitive (allergic) to the active substances, or any of the other ingredients Sinulex® Forte Fizzy Tablets (listed in section 6).
- if you are on immunosuppressant medication since the active substances contained in Sinulex® Forte Fizzy Tablets have an immunostimulant effect (see 'Warnings and precautions').
- without consulting your healthcare provider if you have an existing treatment regimen.

Warnings and precautions

Special care should be taken with Sinulex® Forte Fizzy Tablets:

- if you are on immunosuppressant medication because of the immunostimulant properties of this medicine.
- if you have an autoimmune disease or disorder as Echinacea is known to potentiate antibody responses which may not be suitable for those with autoimmune diseases.
- when pregnant or breastfeeding because safety during pregnancy and lactation has not been established.

Children

Do not give Sinulex® Forte Fizzy Tablets to children who are below the age of 6 years because it is unlikely to be safe. The recommended dosages are specifically calculated to be safe for persons above the age of 6 years only. Keep out of the reach of children.

Other medicines and Sinulex® Forte Fizzy Tablets

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

Sinulex® Forte Fizzy Tablets with alcohol

We do not recommend that you use Sinulex® Forte Fizzy Tablets 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 Fizzy Tablets. 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 Fizzy Tablets contains the following excipients:

- Isomalt 140 mg
- Sodium bicarbonate 80 mg
- Powder lipoxol PEG 6000 80 mg
- Koltidon CL 80 mg
- Tartaric acid 70 mg
- Povidone K25 60 mg

- Sucralose / Acesulfame K 10 mg
- Orange Flavoring 10 mg
- Silicone dioxide 5 mg

3. How to take Sinulex® Forte Fizzy Tablets.

Do not share medicines prescribed for you with any other person. Always take Sinulex® Forte Fizzy Tablets 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 1 tablet, 3 times daily for adolescents over 12, adults, and the elderly; and is the maximum recommended daily and/or total dose.
- The usual dose is ½ tablet, 3 times daily for children over 6 years of age; and is the maximum recommended daily and/or total dose.
- Each dose must be dissolved in a sufficient quantity of liquid (preferably a glass of room temperature water) to and then ingested to ensure safe and proper swallowing/intake of each dissolved tablet.
- Only take this product orally.

If you take more Sinulex® Forte Fizzy Tablets 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 Fizzy Tablets

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

If any of the following happens, stop taking/using Sinulex® Forte Fizzy Tablets 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 Fizzy Tablets. 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 Fizzy Tablets.

5. How to store Sinulex® Forte Fizzy Tablets.

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 Fizzy Tablets 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 Fizzy Tablets 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 Fizzy Tablets looks like and contents of the pack

Sinulex® Forte Fizzy Tablets come in sealed tubes containing either 10 or 12 tablets per tube. The active substances provide a total of 493.71 mg per tablet.

Sinulex® Forte Fizzy Tablets has a tablet dosage form with a specific appearance: Tablet, effervescent, round, pale yellow, 25.5 mm diameter, and no markings. 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 Bruistablette**Sterkte**

493.71 mg per tablet

Farmaseutiese vorm

Bruistablet, oplosbaar, orale

Aktiewe bestanddele

| | |
|----------------------|---------|
| Vitamiën C | 300 mg |
| Echinacea blom | 125 mg |
| Peperwortel | 50 mg |
| Sink glukonaat | 16.7 mg |
| Vitamiën B2 | 2 mg |
| Vitamiën D3 | 8.33 µg |

Bevat suiker en versoeter:

- Isomalt 140 mg
- Sukralose / Acesulfame K..... 10 mg

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 ongeregistreerde 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 Bruistablette 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 Bruistablette ersigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie pamflet. Miskien moet jy dit weer lees.
- Moenie Sinulex® Forte Bruistablette 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

1. Wat Sinulex® Forte Bruistablette is en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy Sinulex® Forte Bruistablette gebruik.
3. Hoe om Sinulex® Forte Bruistablette te neem.
4. Moontlike nuwe-effekte.
5. Hoe om Sinulex® Forte Bruistablette te stoor.
6. Inhoud van die pak en ander inligting.

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

Sinulex® Forte Bruistablette ondersteun die immuunstelsel om allergene, verkoues, griep en sinusitis te hanteer vir beter algemene gesondheid. As gevolg van die aktiewe bestanddele word Sinulex® Forte Bruistablette slegs aangedui vir terapeutiese gebruik vanaf die ouderdom van 6 jaar en ouer. Hierdie aktiewe bestanddele word benut vir simptomatiesse 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 diegene wat asimptomaties is as 'n laerisiko-gesondheidsaanvulling en kan

gebruik word om gesonde vlakke van Vitamiën B2, Vitamiën C, Vitamiën D3 en Sink te handhaaf. Dit is 'n gesondheidsaanvulling wat belangrike immunomodulatoriese en immunostimulerende eienskappe bevat en kan gebruik word om die respiratoriese kanaal en paranasale sinusse ondersteun. Sinulex® Forte Fizzy Tablette word aangedui vir selfadministrasie as 'n lae-riisiko 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. By die gebruik van Sinulex® Forte Bruistablette vir onderhoudsterapie, word dit spesifiek aangedui vir die doeleindes van die handhawing van gesonde vlakke van sy sleutelbestanddele en word nie vir alternatiewe instandhoudingsterapie aangedui nie. Dit word nie aangedui as 'n geneesmiddel of monoterapie vir ernstige toestande nie, want Sinulex® Forte Bruistablette is nie bedoel (of aangedui) om siektes te diagnoseer, te behandel, te voorkom of te genees nie. Dit word streng aangedui vir simptomatiesse verligting as 'n lae-riisiko ondersteunende aanvulling.

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

- as jy hipersensitief (allergies) is vir die aktiewe bestanddele, of enige van die ander bestanddele Sinulex® Forte Bruistablette (gelys in afdeling 6) nie.
- as jy op immuunonderdrukkende medikasie is nie, aangesien die aktiewe bestanddele vervat in Sinulex® Forte Bruistablette 'n immunostimulerende effek het (sien 'Waarskuwings en voorsorgmaatreëls').
- sonder om u gesondheidsorgverskaffer te raadpleeg as u 'n bestaande behandelingsregime het nie.

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet geneem word met Sinulex® Forte Bruistablette:

- as jy op immuunonderdrukkende medikasie is as gevolg van die immunostimulerende eienskappe van hierdie medisyne.
- as jy 'n outo-immuun siekte of wanorde het, aangesien Echinacea bekend is om teenliggaamreaksies te versterk wat dalk nie geskik is vir diegene met outo-immuun siektes nie.
- wanneer jy swanger is of borsvoed omdat veiligheid tydens swangerskap en laktasie nie vasgestel is nie.

Kinders

Moenie Sinulex® Forte Bruistablette aan kinders onder die ouderdom van 6 jaar gee nie, want dit is onwaarskynlik dat dit veilig sal wees. Die aanbevole dosisse word spesifiek bereken om slegs veilig te wees vir persone bo die ouderdom van 6 jaar. Hou buite bereik van kinders.

Ander medisyne en Sinulex® Forte Bruistablette

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

Sinulex® Forte Bruistablette met alkohol

Ons beveel nie aan dat u Sinulex® Forte Bruistablette 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 Bruistablette 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 Bruistablette bevat die volgende eksipiënte:

- Isomalt 140 mg
- Natriumbikarbonaat 80 mg
- Poeier lipoksol PEG 6000 80 mg
- Koltidon CL 80 mg
- Wynsteensuur 70 mg
- Povidone K25 60 mg
- Sukralose / Acesulfame K 10 mg
- Lemoengeur 10 mg
- Silikoondioksied 5 mg

9. Hoe om Sinulex® Forte Bruistablette te gebruik.

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Neem altyd Sinulex® Forte Bruistablette 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 1 tablet, 3 keer per dag vir adolessente ouer as 12, volwassenes en bejaardes; en is die maksimum aanbevole daaglikse en/of totale dosis.
- Die gewone dosis is ½ tablet, 3 keer per dag vir kinders ouer as 6 jaar; en is die maksimum aanbevole daaglikse en/of totale dosis.
- Elke dosis moet opgelos word in 'n voldoende hoeveelheid vloeistof (verkieslik 'n glas kamertemperatuurwater) en dan daarna ingeneem word om veilige en behoorlike sluk / inname van elke opgeloste tablet te verseker.
- Neem slegs hierdie produk mondelings.

As jy meer Sinulex® Forte Bruistablette 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 Bruistablette 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 Bruistablette Kan nuwe-effekte hê. Nie alle nuwe-effekte wat vir Sinulex® Forte Bruistablette gerapporteer word, word in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid vererger of as jy enige nadelige gevolge ervaar terwyl jy Sinulex® Forte Bruistablette neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

As enige van die volgende gebeur, hou op om Sinulex® Forte Bruistablette 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 Bruistablette. 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 Bruistablette.

11. Hoe om Sinulex® Forte Bruistablette 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 Bruistablette 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 Bruistablette 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 Bruistablette lyk en inhoud van die pak

Sinulex® Forte Bruistablette kom in verseëlde buise wat óf 10 of 12 tablette per buis bevat. Die aktiewe bestanddele bied 'n totaal van 493.71 mg per tablet.

Sinulex® Forte Bruistablette het 'n tablet dosis vorm met 'n spesifieke voorkoms: Bruistablet, rond, liggeel, 25.5 mm deursnee, en geen merke. Die karton dien as die sekondêre verpakking vir berging, wat ook die regte etikettering toon.

Houer van Registrasiesertifikaat

Tara Pharmaceuticals (Edms) Bpk

36 Sovereign Drive, Route 21 Corporate Park, Irene, Gauteng, 0062, South Africa

Aansoeknommer

DCFS-db4f9a

Wet 101/1965

Toegang tot ooreenstemmende Professionele Inligting

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