

PATIENT INFORMATION LEAFLET FOR SINULEX® FORTE CAPSULES

SCHEDULING STATUS

S0

SINULEX® FORTE CAPSULES, hard capsules

L-Ascorbic acid (vitamin C), *Armoracia rusticana* G. Gaertn. (horseradish),
zinc sulphate heptahydrate, *Pelargonium sidoides* DC (pelargonium),
cholecalciferol (vitamin D₃).
Sugar free.

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT

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 CAPSULES is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use SINULEX® FORTE CAPSULES carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

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

1. What SINULEX® FORTE CAPSULES is and what it is used for

SINULEX® FORTE CAPSULES may assist in:

- maintaining a healthy respiratory system;
- enhancing the body's natural defense mechanisms;
- strengthening the immune system;
- combatting seasonal allergies, colds, flu, and sinusitis;
- enhancing airway functionality.

2. What you need to know before you take SINULEX® FORTE CAPSULES

Do not take SINULEX® FORTE CAPSULES:

- if you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of SINULEX® FORTE CAPSULES (see **What SINULEX® FORTE CAPSULES contains**).

Warnings and precautions

Take special care with SINULEX® FORTE CAPSULES:

- if you have autoimmune diseases or using prescription immunosuppressants. This medicine has immunostimulant effects; avoid use;
- if you have a planned surgery or dental procedure, avoid using this medication for at least two weeks beforehand. This medicine may thin your blood, which could affect your procedure.

Other medicines and SINULEX® FORTE CAPSULES

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently using:

- anticoagulant medicines (used to prevent your blood from clotting) or herbal supplements with blood thinning effects;
- immunosuppressants (used to treat autoimmune diseases).

SINULEX® FORTE CAPSULES with food, drink and alcohol

See section 3 (**How to take SINULEX® FORTE CAPSULES**).

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before taking SINULEX® FORTE CAPSULES.

Safety and efficacy of SINULEX® FORTE CAPSULES during pregnancy and breastfeeding have not been established.

Do not use SINULEX® FORTE CAPSULES if you are pregnant or breastfeeding your baby.

Driving and using machines

Safety and efficacy when driving or operating machinery have not been established. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how SINULEX® FORTE CAPSULES affects you.

3. How to take SINULEX® FORTE CAPSULES

Do not share your medicines with any other person.

Always take SINULEX® FORTE CAPSULES exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Acute dosage:

Adults and children above the age of 12 years: Take 1 capsule three times daily.

Children 6 – 12 years: Give 1 capsule twice daily.

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

Maintenance dosage:

Adults and children above the age of 12 years: Take 1 capsule twice daily.

Children 6 – 12 years: Give 1 capsule daily.

If you have the impression that the effect of SINULEX® FORTE CAPSULES is too strong or too weak, tell your doctor or pharmacist.

Do not exceed the recommended dosage.

SINULEX® FORTE CAPSULES should be taken after meals.

If you take more SINULEX® FORTE CAPSULES than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining SINULEX® FORTE CAPSULES with you so the doctor will know what you have taken.

4. Possible side effects

SINULEX® FORTE CAPSULES can have side effects.

Not all side effects reported for SINULEX® FORTE CAPSULES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SINULEX® FORTE CAPSULES, please consult your healthcare provider for advice.

If any of the following happens, stop taking SINULEX® FORTE CAPSULES and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SINULEX® FORTE CAPSULES. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain;
- angina;
- changes in the way your heart beats, for example if you notice it beating faster;
- difficulty breathing.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Side effects occurring with an unknown frequency:

- headache;
- flushing (face becomes red and hot);
- nausea (feeling sick);
- vomiting (being sick);
- stomach cramps;
- diarrhoea (runny, loose stools);
- hyperoxaluria (too much oxalate in the urine);
- discomforts of the gastrointestinal tract;
- metallic taste;
- mouth irritation;
- dry mouth;
- hypercalcaemia (too much calcium in the blood);
- hypercalciuria (too much calcium in the urine);
- pruritus (itching);
- rash;
- urticaria (hives).

Side effects occurring with a very rare frequency:

- diarrhoea (runny, loose stools);
- pain or discomfort in the upper abdomen;
- nausea (feeling sick);
- vomiting (being sick);
- dysphagia (difficulty swallowing or feeling like food is stuck in your throat or chest after you swallow);
- mild bleeding of the nose and gums.

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 or pharmacist. 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 CAPSULES.

5. How to store SINULEX® FORTE CAPSULES

- Store all medicines out of reach of children.
- Store at or below 25 °C in a cool, dry place, protected from light.
- Do not store in a bathroom.
- Store in the original packaging.
- Keep the blister strips in the outer box.
- Do not refrigerate or freeze this product.
- Do not use after the expiry date stated on the carton or blisters.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SINULEX® FORTE CAPSULES contains

Each hard capsule contains:

The active substances are:

L-Ascorbic acid (Vitamin C).....	300 mg
<i>Ammoracia rusticana</i> G. Gaertn. (Horseradish).....	50 mg
[root, 4:1 extract equivalent to 200 mg dried herb]	
Zinc sulphate heptahydrate.....	21,8 mg
providing Zinc (elemental).....	4,9 mg
<i>Pelargonium sidoides</i> DC (Pelargonium).....	20 mg
[root, 5:1 extract equivalent to 100 mg dried herb]	
Cholecalciferol (Vitamin D ₃).....	300 I.U. (7,5 µg)

The other ingredients are gelatine (bovine) capsule (yellow/white), maize starch, microcrystalline cellulose (E460), magnesium stearate (E572) and silicon dioxide (E551).

What SINULEX® FORTE CAPSULES looks like and contents of the pack

Hard capsules.

Size 0 gelatine capsules (bovine) with a yellow cap and opaque white body, containing an off-white to light brown powder.

3 capsule pack size: 3 capsules packed in a printed foil sachet/pouch.

10 capsule pack size: blister pack of 10 capsules, and a patient information leaflet, packed in a printed outer carton.

30 capsule pack size: 3 blister packs of 10 capsules, and a patient information leaflet, packed in a printed outer carton.

Holder of Certificate of Registration

Brunel Laboratoria (Pty) Ltd

1 Van Tonder Street

Sunderland Ridge

Centurion

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This leaflet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

Access to the corresponding Professional Information

The Professional Information for SINULEX® FORTE CAPSULES is available on

<https://www.brunel.co.za/professional-information/> or can be requested from the contact details above.

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PASIËNTINLIGTINGSBLAD VIR SINULEX® FORTE CAPSULES

SKEDULERINGSSTATUS

S0

SINULEX® FORTE CAPSULES, harde kapsules

L-Askorbiensuur (vitamien C), *Armoracia rusticana* G. Gaertn. (peperwortel),
sinksulfaatheptahidraat, *Pelargonium sidoides* DC (pelargonium),
cholekalsiferol (vitamien D₃).
Suikervry.

KOMPLEMENTÊRE MEDISYNE: KOMBINASIEPRODUK

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

Lees hierdie hele inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir jou.

SINULEX® FORTE CAPSULES is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te onderhou. Nietemin, moet jy SINULEX® FORTE CAPSULES versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.
- Jy moet 'n dokter sien as jou simptome vererger of nie verbeter na 10 dae nie.

Wat is in hierdie inligtingsblad

1. Wat SINULEX® FORTE CAPSULES is, en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy SINULEX® FORTE CAPSULES neem.
3. Hoe om SINULEX® FORTE CAPSULES te neem.
4. Moontlike nuwe-effekte.
5. Hoe om SINULEX® FORTE CAPSULES te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat SINULEX® FORTE CAPSULES is, en waarvoor dit gebruik word

SINULEX® FORTE CAPSULES mag help met:

- die handhawing van 'n gesonde respiratoriese stelsel;
- die versterking van die liggaam se natuurlike verdedigingsmeganismes;
- die versterking van die immuunstelsel;
- die bestryding van seisoenale allergieë, verkoues, griep, en sinusitis;
- die verbetering van lugwegfunksionaliteit.

2. Wat jy moet weet voordat jy SINULEX® FORTE CAPSULES neem

Moet nie SINULEX® FORTE CAPSULES neem:

- indien jy hipersensitief (allergies) is vir enige van die aktiewe bestanddele of vir enige van die ander bestanddele van SINULEX® FORTE CAPSULES nie (sien **Wat SINULEX® FORTE CAPSULES bevat**).

Waarskuwings en voorsorgmaatreëls

Wees versigtig met SINULEX® FORTE CAPSULES:

- indien jy 'n outo-immuun siektes het of voorskrif immuunonderdrukkers gebruik. Hierdie medisyne het immunostimulerende effekte; vermy gebruik;
- As jy 'n beplande operasie of tandheelkundige prosedure het, vermy die gebruik van hierdie medikasie vir ten minste twee weke vooraf. Hierdie medisyne kan jou bloed verdun, wat jou prosedure kan beïnvloed.

Ander medisyne en SINULEX® FORTE CAPSULES

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

Sê vir jou dokter of apteker indien jy tans die volgende gebruik:

- teenstolmiddels (gebruik om te keer dat jou bloed klonte vorm) of kruieaanvullings met bloedverduunnende effekte;
- immuunonderdrukkers (gebruik om outo-immuun siektes te behandel).

SINULEX® FORTE CAPSULES met eet-, drinkgoed en alkohol

Sien afdeling 3 (**Hoe om SINULEX® FORTE CAPSULES te neem**).

Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy SINULEX® FORTE CAPSULES neem. Dit is nie vasgestel of SINULEX® FORTE CAPSULES veilig en doeltreffend is om tydens swangerskap en borsvoeding te gebruik nie.

Moet nie SINULEX® FORTE CAPSULES gebruik indien jy swanger is of jou baba borsvoed nie.

Bestuur en die gebruik van masjiene

Dit is nie vasgestel of SINULEX® FORTE CAPSULES veilig en doeltreffend is tydens bestuur en gebruik van masjiene nie. Moet nie 'n voertuig bestuur, masjiene hanteer, of enigiets anders doen wat jou aandag vereis totdat jy weet hoe SINULEX® FORTE CAPSULES jou affekteer nie.

3. Hoe om SINULEX® FORTE CAPSULES te neem

Moet nie jou medisyne met enige ander persoon deel nie.

Neem SINULEX® FORTE CAPSULES altyd presies soos aangedui in hierdie inligtingsblad, of soos jou dokter of apteker vir jou verduidelik het. Vra gerus vir jou dokter of apteker indien jy onseker is.

Die gewone dosis is:

Akute dosering:

Volwassenes en kinders ouer as 12-jarige ouderdom: Neem 1 kapsule drie keer per dag.

Kinders 6 – 12 jaar: Gee 1 kapsule twee keer per dag.

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

Onderhoudsdosering:

Volwassenes en kinders ouer as 12-jarige ouderdom: Neem 1 kapsule twee keer per dag.

Kinders 6 – 12 jaar: Gee 1 kapsule daaglik.

As jy die indruk kry dat die effek van SINULEX® FORTE CAPSULES te sterk of te swak is, vertel jou dokter of apteker.

Moet nie die aanbevole dosis oorskry nie.

SINULEX® FORTE CAPSULES moet na etes geneem word.

As jy meer SINULEX® FORTE CAPSULES neem as wat jy moet

In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie inligtingsblad en die oorblywende SINULEX® FORTE CAPSULES saam met jou sodat die dokter kan sien wat jy geneem het.

4. Moontlike nuwe-effekte

SINULEX® FORTE CAPSULES kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir SINULEX® FORTE CAPSULES gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy SINULEX® FORTE CAPSULES neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om SINULEX® FORTE CAPSULES te neem en sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk of asemhaling;
- uitslag of gejeuk;
- floute.

Hierdie is baie ernstige newe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op SINULEX® FORTE CAPSULES gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Vertel jou dokter onmiddellik of gaan na die naaste ongevalle-afdeling by jou naaste hospitaal as jy een van die volgende opmerk:

- borspyn;
- angina;
- veranderinge in die manier waarop jou hart klop, byvoorbeeld as jy opmerk dat dit vinniger klop;
- asemhalingsprobleme.

Hierdie is ernstige newe-effekte. Jy kan dringend mediese hulp benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Newe-effekte wat met 'n onbekende frekwensie voorkom:

- hoofpyn;
- blosing (gesig word rooi en warm);
- naarheid;
- braking;
- maagkrampe;
- diarree (loperige, los stoelgange);
- hiperoksalurie (te veel oksalaat in die urine);
- ongemak van die spysverteringskanaal;
- metaal smaak;
- mond irritasie;
- droë mond;
- hiperkalsemie (te veel kalsium in die bloed);
- hiperkalsiurie (te veel kalsium in die urine);
- pruritus (jeuk);
- uitslag;
- urtikaria (korwe/galbulte).

Newe-effekte wat met 'n baie seldsame frekwensie voorkom:

- diarree (loperige, los stoelgange);
- pyn of ongemak in die boonste area van die buik;
- naarheid;
- braking;
- disfagie (sukkel om te sluk of voel asof kos in jou keel of bors vassit nadat jy gesluk het);
- ligte bloeding van die neus en tandvleis.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Aanmelding van newe-effekte

Indien jy newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die “**6.04 Adverse Drug Reaction Reporting Form**”, wat aanlyn by **SAHPRA se publikasies** beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van SINULEX® FORTE CAPSULES te verskaf.

5. Hoe om SINULEX® FORTE CAPSULES te bêre

- Bêre alle medisyne buite die bereik van kinders.
- Bêre teen of onder 25 °C, in 'n koel, droë plek, beskerm teen lig.
- Moet nie in die badkamer bêre nie.
- Bêre in die oorspronklike verpakking.
- Bêre die stulpstrokies in die karton.
- Moet nie hierdie produk in die yskas of vrieskas bêre nie.
- Moet nie gebruik na die vervaldatum soos aangedui op die karton of die stulpstrokies nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moet nie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat SINULEX® FORTE CAPSULES bevat

Elke harde kapsule bevat:

Die aktiewe bestanddele is:

L-Askorbiensuur (Vitamien C).....	300 mg
<i>Armoracia rusticana</i> G. Gaertn. (Peperwortel).....	50 mg
[wortel, 4:1 ekstrak lewer 200 mg gedroogde kruie ekwivalent]	
Sinksulfaatheptahidraat.....	21,8 mg
lewer Sink (elementaal).....	4,9 mg
<i>Pelargonium sidoides</i> DC (Pelargonium).....	20 mg
[wortel, 5:1 ekstrak lewer 100 mg gedroogde kruie ekwivalent]	
Cholekalsiferol (Vitamien D ₃).....	300 I.U. (7,5 µg)

Die ander bestanddele is gelatien (bees) kapsule (geel/wit), mieliestysel, mikrokristallyne sellulose (E460), magnesiumstearaat (E572) en silikondioksied (E551).

Hoe SINULEX® FORTE CAPSULES lyk en inhoud van die verpakking

Harde kapsules.

Grootte 0 gelatienkapsules (bees) met 'n geel doppie en ondeursigtige wit romp, wat 'n naaswit tot ligbruin poeier bevat.

3 kapsule pakgrootte: 3 kapsules verpak in 'n gedrukte foelie sakkie.

10 kapsule pakgrootte: stulpstrook met 10 kapsules, saam met 'n pasiëntinligtingsblad, verpak in 'n gedrukte buitekarton.

30 kapsule pakgrootte: 3 stulpstroke met 10 kapsules elk, saam met 'n pasiëntinligtingsblad, verpak in 'n gedrukte buitekarton.

Houer van die Registrasiesertifikaat

Brunel Laboratoria (Edms) Bpk

Van Tonderstraat 1

Sunderland Ridge

Centurion

0157

info@brunel.co.za

Hierdie inligtingsblad is hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad

Die Professionele Inligtingsblad vir SINULEX® FORTE CAPSULES is beskikbaar by

<https://www.brunel.co.za/professional-information/> of dit kan aangevra word deur die kontakbesonderhede hier bo te gebruik.

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