

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

SINUPLEX[®], 120 Tablets

COMPOSITION

Each one (1) tablet of SINUPLEX[®] contains the following actives:

Quercetin	200 mg
Vitamin C (as ascorbic acid)	150 mg
Stinging Nettle (<i>Urtica dioica</i>) [Root 7:1 Extract]	100 mg
Bromelain	1 800 000 FCC PU
L-Cysteine (as N-acetyl-L-cysteine)	25 mg

Inactive Ingredients: Coating (hypromellose, medium-chain triglycerides, and hydroxypropylcellulose), croscarmellose sodium, magnesium stearate (vegetable), microcrystalline cellulose and silica.

This product is suitable for non-GMO, gluten & dairy free (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

SINUPLEX[®] may help relieve seasonal allergy symptoms, thereby supporting healthy respiratory function. It also plays a role in maintaining normal immune response to seasonal allergens.

Ingredient	Uses for Ingredient
Quercetin	Antioxidant and anti-inflammatory; used to support immune health and reduce allergy symptoms.
Vitamin C (as ascorbic acid)	Essential vitamin for immune support, skin health, and antioxidant protection.
Stinging Nettle (<i>Urtica dioica</i>)	Traditionally used for joint health, urinary tract issues, and as an anti-inflammatory.
Bromelain	Enzyme derived from pineapple; used for reducing inflammation, improving digestion, and as a mucolytic.
L-Cysteine (as N-acetyl-L-cysteine)	Antioxidant that supports liver health, detoxification, and respiratory health.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take SINUPLEX[®] if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement. **Surgery:** SINUPLEX[®] might increase the risk of bleeding during and after surgery. Stop using SINUPLEX[®] at least 2 weeks before a scheduled surgery.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See Warnings & Special precautions)

DOSAGE AND DIRECTIONS FOR USE

Adults: Take one (1) tablet daily or as directed by your healthcare practitioner. **Do not take more than the recommended dose.**



KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects.

Treatment: Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: kidney stones or kidney disease. If you are taking the following medication, please consult with your healthcare professional before taking: May interact with blood thinners (e.g., Warfarin), chemotherapy drugs, blood pressure, diabetes, and diuretics (increased effect), nitroglycerin (increased blood pressure-lowering effects). If any of the following happens, stop using SINUPLEX[®] and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions— rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing: These are all very serious effects. If you have them, you may have had a serious reaction to SINUPLEX[®]. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- Gastrointestinal upset, headache, abdominal pain. These are all very serious effects. If you have them, you may have had a serious reaction to SINUPLEX[®]. You may need urgent medical attention or hospitalisation. Seek advice from a healthcare professional if you have any medical condition. Discontinue use immediately should any adverse reaction occur. Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.
- Keep this leaflet. You may need to read it again.
- Do not share medication with any other person.
- Ask your pharmacist if you need more information or advice.
- You must consult a doctor should your condition worsen or does not improve. **DO NOT USE THIS PRODUCT:**
- If you are hypersensitive (allergic) to any of the ingredients listed.
- Do not accept this package if seals are broken.

STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original bottle.

Keep the bottle tightly closed.

Replace the protective cap after each use.

Do not use after the expiry date stated on the bottle.

Do not use SINUPLEX[®] if you notice visible signs of deterioration.

IDENTIFICATION

Beige, speckled, coated caplet.

PRESENTATION

A white 250 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

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

NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by: Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,
Sandton, 2146, Tel: 011-802-8101

DATE OF PUBLICATION

To be allocated by the regulatory authority.

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PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Dissiplinespesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

SINUPLEX®, 120 Tablette

SAMESTELING

Elke een (1) tablet van SINUPLEX® bevat die volgende aktiewe stowwe:

Quercetin	200 mg
Vitamiene C (as askorbien-suur)	150 mg
Brandnetel (Urtica dioica) [Wortel 7:1 Uittreksel]	100 mg
Bromelain	1 800 000 FCC PU

L-sisteine (as N-asetiel-L-sisteien) 25 mg

Onaktiewe bestanddele: Laag (hipromellose, mediumketting trigliseriede, en hidroksipropylselulose), croscarmellose-natrium, magnesium stearaat (groente), mikrokristallyne selulose en silika.

Hierdie produk is geskik vir nie-GGO, gluten en suiwelvry (suikervry)

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

SINUPLEX® kan help om seisoenale allergiesimptome te verlig en sodoende gesonde respiratoriese funksie te ondersteun. Dit speel ook 'n rol in die handhawing van normale immunerespons op seisoenale allergene.

Bestanddeel	Gebruik vir bestanddeel
Quercetin	Antioksidant en anti-inflammatories; Word gebruik om immuugesondheid te ondersteun en allergiesimptome te verminder.
Vitamiene C (as askorbien-suur)	Noodsaklike vitamiene vir immuonondersteuning, velgesondheid en antioksidantbeskerming.
Brandnetel (Urtica dioica)	Tradisioneel gebruik vir gesamentlike gesondheid, urienewegkwessies, en as 'n anti-inflammatoriese middel.
Bromelain	Ensiem afkomstig van pynappel; Word gebruik vir die vermindering van inflammasie, die verbetering van spysvertering en as 'n mukolitiese.
L-sisteine (as N-asetiel-L-sisteien)	Antioksidant wat lewergesondheid, ontgifting en respiratoriese gesondheid ondersteun.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidspraktisyn te raadpleeg nie. Moenie SINUPLEX® neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidspraktisyn gaan voordat jy hierdie aanvulling neem. **Chirurgie:** SINUPLEX® kan die risiko van bloeding tydens en na die operasie verhoog. Hou op om SINUPLEX® ten minste 2 weke voor 'n geskeduleerde operasie te gebruik.

INTERAKSIES

Vertel altyd jou gesondheidspraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne 'n interaksie mag hê. (**Sien Waarskuwings en Spesiale voorsorgmaatreëls**)

DOSIS EN AANWYSINGS VIR GEBRUIK

Volwassenes: Neem een (1) tablet daagliks of soos voorgeskryf deur jou gesondheidspraktisyn.

Moenie meer as die aanbevole dosis neem nie.

WAARSKUWING EN SPESIALE VOORSORGMAATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidspraktisyn voor gebruik: nierstene of niersekte. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Kan interaksie hê met bloedverdunner (bv. Warfarin), chemoterapiemiddels, bloeddruk, diabetes en diuretika (verhoogde effek), nitroglycerien (verhoogde bloeddrukverlagende effekte). As enige van die volgende gebeur, hou op om SINUPLEX® te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Allergiese reaksies- uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling;

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op SINUPLEX® gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê. **Nuwe-effekte** wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidspraktisyn as hulle voortduur):

- Gastro-intestinale ontsteltenis, hoofpyn, buikpyn.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op SINUPLEX® gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

Raadpleeg 'n gesondheidspraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind. Lees hierdie inligtingsblad aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie medisyne met enige ander persoon deel nie.
- Vra jou apteker of jy meer inligting of advies benodig.
- Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.

MOENIE HIERDIE PRODUK GEBRUIK NIE:

- As jy hipersensitief (allergies) is vir enige van die bestanddele wat gelys word.
- Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidspraktisyn vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidspraktisyn in kennis.

BEKENDE SIMPTOME VAN OORDOESING EN BESONDERHEDE VAN DIE

BEHANDELING DAARVAN

Sien nuwe-effekte.

Behandeling: Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidspraktisyn vir advies.

BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C. B

eskerm teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.

Moenie SINUPLEX® gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Beige, gespikkelde, bedekte caplet.

AANBIEDING

'n Wit 250 ml HDPE-bottel met 'n wit dop, induksiesêl, peuterkrimpseël, spons en silikagelsakkie.

REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

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

NAAM EN BESIGHEIDSADRES VAN APPLIKANT

Versprei deur:

Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road,
Eastgate Extension, Sandton, 2146, Tel: 011- 802-8101

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.