

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### SINUPLEX<sup>®</sup>, 120 Tablets

#### READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

- **SINUPLEX<sup>®</sup>** is available without a doctor's prescription.
- Nevertheless, you still need to use **SINUPLEX<sup>®</sup>** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **SINUPLEX<sup>®</sup>** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

#### WHAT IS IN THIS LEAFLET

- What **SINUPLEX<sup>®</sup>** is and what it is used for.
- What you need to know before you take **SINUPLEX<sup>®</sup>**.
- How to take **SINUPLEX<sup>®</sup>**.
- Possible side effects.
- How to store **SINUPLEX<sup>®</sup>**.
- Contents of the pack and other information.

#### WHAT SINUPLEX<sup>®</sup> CONTAINS

Each one (1) tablet of **SINUPLEX<sup>®</sup>** 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)**

#### WHAT SINUPLEX<sup>®</sup> IS AND WHAT IT IS USED FOR

**SINUPLEX<sup>®</sup>** may help relieve seasonal allergy symptoms, thereby supporting healthy respiratory function. It also plays a role in maintaining normal immune response to seasonal allergens.

#### BEFORE YOU TAKE SINUPLEX<sup>®</sup>

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. Do not take **SINUPLEX<sup>®</sup>** 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<sup>®</sup>** might increase the risk of bleeding during and after surgery. Stop using **SINUPLEX<sup>®</sup>** at least 2 weeks before a scheduled surgery.

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

#### PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has not been established, consult with your healthcare professional before use. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare professional before taking this supplement.

#### DRIVING AND USING MACHINES

It is not always possible to predict to what extent **SINUPLEX<sup>®</sup>** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **SINUPLEX<sup>®</sup>** may affect you.

#### TAKING OTHER MEDICINES WITH SINUPLEX<sup>®</sup>

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your medical practitioner.



#### HOW TO TAKE SINUPLEX<sup>®</sup>

Do not share medicines prescribed for you with any other person. Always take **SINUPLEX<sup>®</sup>** exactly as described in this leaflet, or as your doctor, healthcare provider has instructed you. You should check with your doctor, pharmacist or healthcare provider if you are unsure.

#### Directions for use:

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

#### IF YOU TAKE MORE SINUPLEX<sup>®</sup> THAN YOU SHOULD

In the event of overdose, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.

#### IF YOU FORGET TO TAKE SINUPLEX<sup>®</sup>

Do not take a double dose to make up for a missed dose.

#### POSSIBLE SIDE EFFECTS

**SINUPLEX<sup>®</sup>** may have side effects.

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 practitioner 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<sup>®</sup>** 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<sup>®</sup>**. 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.

Not all side effects and interactions reported for **SINUPLEX<sup>®</sup>** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

#### REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "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 **SINUPLEX<sup>®</sup>**.

#### STORAGE AND DISPOSING OF SINUPLEX<sup>®</sup>

Store all medicines out of the reach of children.

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

Protect from direct sunlight and heat.

Store in the original packaging.

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

Do not use **SINUPLEX<sup>®</sup>** if you notice visible signs of deterioration.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

#### PRESENTATION OF SINUPLEX<sup>®</sup>

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

#### IDENTIFICATION OF SINUPLEX<sup>®</sup>

Beige, speckled, coated tablet.

#### REGISTRATION NUMBER –

To be allocated by SAHPRA upon registration.

#### ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

#### THIS LEAFLET WAS LAST REVISED ON

21 January 2025

#### NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

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# PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS **50**

Kategorie D: Komplementêre medisyne.

Dissipline: Dissiplinespesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

## SINUPLEX<sup>®</sup>, 120 Tablette

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BELANGRIKE INLIGTING VIR U

- **SINUPLEX<sup>®</sup>** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **SINUPLEX<sup>®</sup>** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **SINUPLEX<sup>®</sup>** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisynt van jy meer inligting of advies benodig.

WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **SINUPLEX<sup>®</sup>** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **SINUPLEX<sup>®</sup>** neem.
- Hoe om **SINUPLEX<sup>®</sup>** te neem.
- Moontlike nuwe-effekte.
- Hoe om **SINUPLEX<sup>®</sup>** te bêre.
- Inhoud van die pak en ander inligting

WAT IS **SINUPLEX<sup>®</sup>** KAPSULEN EN WAARVOOR WORD DIT GEBRUIK

**SINUPLEX<sup>®</sup>** help om seisoenale allergieë simptome te hêrleef en soodoende gesonde respiratoriese funksie te ondersteun. Dit speel ook 'n rol in die handhawing van normale immuunrespons op seisoenale allergene.

VOORDAT JY **SINUPLEX<sup>®</sup>** NEEM

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

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

BESTUUR EN GEBRUIK VAN MASIËNE

Dit is nie altyd moontlik om te voorspel in watter mate **SINUPLEX<sup>®</sup>** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die vereiste van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjien/toerusting, totdat hulle bewus is van die mate waartoe **SINUPLEX<sup>®</sup>** jou beïnvloed.

WATER **SINUPLEX<sup>®</sup>** BEVAT

Elke een (1) tablet **SINUPLEX<sup>®</sup>** bevat die volgende aktiewe:

Quercetin	200 mg
Vitamiën C (as askorbienium)	150 mg
Brandnetel (Urtica dioica) [Wortel 7:1 Uittreksel]	100 mg
Bromelain	1 800 000 FCC PU
L-sistein (as N-asetiel-L-sistein)	25 mg

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

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

NEEM VAN ANDER MEDISYNE SAAM MET **SINUPLEX<sup>®</sup>**

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisynt te raadpleeg nie.

**SWANGERSKAP EN BORSVOEDING**

Alhoewel veiligheid tydens swangerskap en borsvoeding vasgestel is, raadpleeg u gesondheidsorgpraktisynt vir gebruik. As u swanger is of borsvoed, dink dat u swanger is of beplan om 'n baba te hê, raadpleeg u gesondheidsorgpraktisynt voordat u hierdie aanvulling neem.

**HOE OM **SINUPLEX<sup>®</sup>** TE NEEM**

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **SINUPLEX<sup>®</sup>** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktisynt voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisynt as jy onseker is.

**Aanwysings vir gebruik:**

**Volwasse:** Neem een (1) tablet daaglik of soos voorgeskryf deur jou gesondheidsorgpraktisynt.

**Moenie meer as die aanbevole dosis neem nie.**

**AS JY MEER **SINUPLEX<sup>®</sup>** NEEM AS WAT JY MOET**

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

**AS JY VERGET OM **SINUPLEX<sup>®</sup>** TE NEEM**

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.

**MOONTLIKE NUWE-EFFEKTE**

**SINUPLEX<sup>®</sup>** kan nuwe-effekte hê.

Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisynt vir gebruik: : nierstene of niersekte. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisynt voordat jy neem: Kan interaksie hê met bloedverdunder (bv. Warfarin), chemoterapiemiddels, bloeddruk, diabetes en diuretika (verhoogde effek), nitroglyserien (verhoogde bloeddruklagende effekte). As enige van die volgende gebeur, hou op om **SINUPLEX<sup>®</sup>** te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Allergiese reaksie-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<sup>®</sup>** gehad. Jy mag dalk dringende mediese hulp of hospitalisasie nodig hê.

Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteur aan u gesondheidsorgpraktisynt as dit voortduur):

- Gastro-intestinale ontsteltelien, hoofpyn, buikpyn.

Nie alle nuwe-effekte en interaksies wat vir **SINUPLEX<sup>®</sup>** gerapporteer word, is by hierdie inligtingsblad ingesluit nie. 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 gesondheidsorgpraktisynt vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisynt in kennis.

**AANMELDING VAN NUWE-EFFEKTE**

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisynt. U kan ook nuwe-effekte aan SAHPRA rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies:

<https://www.sahpra.org.za/publications/index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **SINUPLEX<sup>®</sup>**.

**HOE OM **SINUPLEX<sup>®</sup>** TE BÊRE**

Bêre alle medisyne buite bereik van kinders.

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

Beskermt teen direkte sonlig en hitte.

Bêre in die oorspronklike verpakking.

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

Moenie **SINUPLEX<sup>®</sup>** gebruik as u sigbare tekens van agteruitgang opmerk nie.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

**AANBIEDING VAN **SINUPLEX<sup>®</sup>****

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

**IDENTIFIKASIE VAN **SINUPLEX<sup>®</sup>****

Beige, gespikkelde, bedekte caplet.

**REGISTRASIE NOMMER**

Om deur SAHPRA toegeken te word by registrasie.

**TOEGANG TOT DIE OOREENSTEMMENDE PROFESIONELE INLIGTING**

Skandeer QR-kode.

**HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP**

21 Januarie 2025

**NAAM EN ADRES VAN REGISTRASIEHOUDER**

Versprei deur:

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