

PASIËNTINLIGTINGSBLAD

Inligting vir die Pasiënt rakende

SINUFIX FORTE

Lees die hele inligtingsblad deeglik voordat u begin om SINUFIX FORTE te gebruik, want dit bevat inligting wat belangrik is vir u.

Hierdie produk is beskikbaar sonder 'n dokter se voorskrif. U moet egter steeds die SINUFIX FORTE versigtig gebruik om die beste resultate daarmee te verkry.

• Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.

• Indien u verdere vrae het, vra asseblief u dokter of apteker.

• U moet 'n dokter raadpleeg indien u simptome vererger of nie beter word nie.

• Moenie SINUFIX FORTE met enige ander persoon deel nie.

• Hierdie medisyne is nie deur die Medisynebeheerraad geëvalueer nie. Hierdie medisyne is nie bedoel om enige siekte te diagnoseer, behandel, genees of te voorkom nie.

SKEDULERINGSSTATUS:

Ongeskeduleerd.

EIENDOMSNAAM (EN DOSEERVORM):

SINUFIX FORTE

(Harde gelatienekapsules)

FARMAKOLOGIESE KLASSEKASIE:

D 5.8 Middels vir verkoue, insluitende nasale ontstuwingsmiddels

WAT SINUFIX FORTE BEVAT:

Elke SINUFIX FORTE kapsule bevat:

Bestanddeel	Hoeveelheid
Geel gentiaan (<i>Gentiana lutea</i>) wortel	12 mg
Primula (<i>Primula veris</i>) blom met kelk	36 mg
Boksurting (<i>Rumex acetosa</i>) kruie	36 mg
Europese vlier (<i>Sambucus nigra</i>) blomme	36 mg
Ysterkruid (<i>Verbena officinalis</i>) kruie	36 mg

Onaktiewe bestanddele sluit in dikalsiumfosfaat, magnesiumstearaat, stysel en Tokusil® (gepresipiteerde silika).

SINUFIX FORTE is in 'n kapsule wat hlaal-gesertifiseerde gelatien bevat. Dit bevat nie kunsmatige geur- en kleurmiddels, kaffeïen, gluten, laktose, preserveermiddels, tartrasien en bygevoegde gis nie.

WAARVOOR SINUFIX FORTE GEBRUIK WORD:

SINUFIX FORTE is 'n kruie-middel om die simptome van ligte boonste lugweginfeksies en sinusitis te verlig. Dit werk deur die sinusse te bevogtig en normale sinusfunksie te herstel. Dit verbeter ook lugvloei in die neusgange en sinusse deur te help met die opruiming van mukus uit die neus en sinusse.

SINUFIX FORTE mag ook simptome verlig wat verband hou met die ontsteking van die sinusse en boonste lugweg.

VOORDAT U SINUFIX FORTE NEEM:

MOET NIE SINUFIX FORTE NEEM NIE:

- Indien u allergies (hipersensitief) is vir enige van die aktiewe of onaktiewe bestanddele in die formulering.
- Indien u swanger is of u baba borsvoed (sien "Swangerskap en borsvoeding").
- **SINUFIX FORTE** moet nie gebruik word deur kinders wat jonger as 12 jaar oud is nie. Kinders jonger as 12 kan wat vloeistofdoseervorm gebruik (**SINUFIX SYRUP**).

Neem spesiale sorg met SINUFIX FORTE:

SINUFIX FORTE moet nie gebruik word om enige medisyne wat deur u dokter voorgeskryf is, te vervang nie. Raadpleeg u dokter indien u voorskryfmedisyne neem (sien "Die neem van SINUFIX FORTE saam met ander medisyne").

Bespreek asseblief die gebruik van **SINUFIX FORTE** met u dokter indien u:

- Met enige van die volgende toestande diagnoseer is:
 - o Lae bloeddruk, aangesien gentiaan u lae bloeddruk mag vererger of inmeng met terapie om bloeddruk te verhoog.
 - o Hoë of lae bloeddruk, aangesien hoë dosisse **SINUFIX FORTE** mag inmeng met die beheer van hierdie toestande.
 - o Maagseer.
 - o Gastro-intestinale steurings, wat gastritis, ontsteking van die kolon, ens. insluit.
 - o Niersiekte, veral nierstene, aangesien groot hoeveelhede boksurting (*Rumex acetosa*) die risiko vir nierstene mag verhoog.
 - o Outoïmmuunsiekte, aangesien blomme van die vlier (*Sambucus nigra*) outoïmmuunsiekte mag stimuleer om aktief te raak.
- Geskeduleer is vir chirurgie. Onthou om u dokter of narkotiseur in te lig dat u **SINUFIX FORTE** neem.
- Geskeduleer is om bloettoets te laat doen. Onthou om u professionele gesondheidsorgwerker in te lig dat u **SINUFIX FORTE** neem.

MOET NIE enige ander voedings- of kruie-aanvullings neem sonder om vooraf hul gesamentlike gebruik met **SINUFIX FORTE** met u dokter of apteker te bespreek nie (sien "Die neem van **SINUFIX FORTE** saam met ander medisyne").

Verseker dat u binne die aanbevole doseringsriglyne bly.

Die neem van SINUFIX FORTE met kos en drinkgoed:

SINUFIX FORTE kan met of sonder kos geneem word.

Swangerskap en borsvoeding:

Moet NIE **SINUFIX FORTE** neem terwyl u swanger is of u baba borsvoed nie, aangesien die veiligheid nie bepaal is nie (sien "Moet NIE **SINUFIX FORTE** neem NIE"). **SINUFIX FORTE** mag slegs tydens swangerskap of borsvoeding gebruik word nádat die dokter al die risiko's betrokke geëvalueer het en steeds voel dat dit tot voordeel vir u gesondheid sal wees.

Indien u swanger is of u baba borsvoed terwyl **SINUFIX FORTE** geneem word, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker.

Bestuur en die gebruik van masjinerie:

Dit is onwaarskynlik dat **SINUFIX FORTE** u vermoë om te bestuur of masjinerie te hanteer, sal beïnvloed. Indien u egter nuwe-effekte soos duiseligheid, lighoofdigheid of wasige visie ontwikkel, moet u dit vermy om 'n voertuig te bestuur of masjinerie te hanteer.

Die neem van SINUFIX FORTE saam met ander medisyne:

Indien u ander medisyne op 'n gereelde grondslag neem, insluitend komplementêre of tradisionele medisyne, mag die gebruik van **SINUFIX FORTE** saam met hierdie medisyne ongewenste wisselwerkings veroorsaak. Raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker.

Bespreek asseblief die gebruik van die volgende medisyne of middels in kombinasie met **SINUFIX FORTE** met u dokter of apteker:

- Bloeddrukverlagende aanvullings of medikasie, soos: kaptopriël, enalapriël, losartaan, valsartaan, diltiasem, amlodipien, hidrochlorotiasied, furosemied en vele ander; aangesien dit die bloeddrukverlagende effek mag versterk.
- Kalsium, yster en sink, aangesien die gelyktydige gebruik saam met boksurting (*Rumex acetosa*) die absorpsie van hierdie minerale uit die gastro-intestinale weg mag verlaag.
- Immunoonderdrukkende middels, insluitend asiatiopien, basiliësimab, siklosporien, daklimumab, muromonab-CD3, mikofenolaat, takrolimus, sirolimus, prednison en enige ander kortikosteroïede, aangesien vlier (*Sambucus nigra*) mag inmeng met immunoonderdrukkertherapie weens die immuunstimulerende aktiwiteit daarvan.
- Die rook van tabak moet gestaak word tydens die gebruik van **SINUFIX FORTE** aangesien dit die effektiwiteit van die behandeling verminder.

HOE OM SINUFIX FORTE TE NEEM:

Neem 1 (een) kapsule 3 (drie) keer per dag met 'n glas water voor of na 'n maaltyd, of soos aangedui deur u dokter.

MOET NIE DIE AANBEVENE DAAGLIKSE DOSIS OORSKRY NIE.

SINUFIX FORTE moet nie vir meer as 7 – 14 dae geneem word nie. Indien u simptome langer as 7 – 14 dae voortduur of terugkeer ná die gebruik van **SINUFIX FORTE**, moet u 'n dokter raadpleeg.

Raadpleeg u dokter indien simptome voortduur of indien dit met 'n styging in liggaamstemperatuur (koors) gepaardgaan.

Indien u die indruk kry dat die effek van **SINUFIX FORTE** te sterk of te swak is, praat asseblief met u dokter of apteker daaroor.

Indien u meer SINUFIX FORTE neem as wat u behoort:

Indien u meer **SINUFIX FORTE** neem as wat u behoort, mag u 'n toename in die nuwe-effekte wat hier onder gelys is ervaar (sien "MOONTLIKE NUWE-EFFEKTE").

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, verkry onmiddellik hulp by die naaste hospitaal of gifbeheersentrum.

Tot op datum is geen geval van oordosering met **SINUFIX FORTE** kapsules aangemeld nie.

Indien u vergeet om SINUFIX FORTE te neem:

Neem **SINUFIX FORTE** altyd soos aangedui. Indien u 'n dosis oorsaan, neem dit so gou as wat u onthou. Indien u nie die oorgeslane dosis onthou voordat dit tyd is vir die volgende dosis nie, slaan die dosis wat vergeet is oor en keer terug na u gewone doseringskedule van een kapsule drie keer per dag. Moet nie 'n dubbele dosis neem om te vergoed vir die vergeete individuele dosisse nie.

MOONTLIKE NUWE-EFFEKTE:

SINUFIX FORTE mag nuwe-effekte hê. Nie alle nuwe-effekte wat vir **SINUFIX FORTE** aangemeld is, word in hierdie inligtingsblad ingesluit nie. Indien u algemene gesondheid versleg terwyl **SINUFIX FORTE** geneem word, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker.

Nuwe-effekte wat mag voorkom sluit in:

- Gastro-intestinale steurings, insluitend naarheid, braking, diarree of maagpyn.
- Allergiese velreaksies, insluitend grootskaalse jeuk en rooiheid.
- Swakheid, duiseligheid en verminderde gevoeligheid.
- Loopneus en kortasemheid.
- Allergiese reaksies, soos swelling van die vel en gesig.

Raadpleeg u dokter of apteker indien u enige nuwe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie.

BERGING EN WEGDOENING VAN SINUFIX FORTE:

Bêre by of benede 25 °C.
Beskerm teen hitte en lig.
Moenie die kapsule neem ná die vervaldatum wat op die verpakking is nie.

Neem alle ongebruikte kapsules terug na u apteker. Hou die stulpstrokke in die buitenste karton tot benodig vir gebruik. Moenie ongebruikte kapsules in dreine of rioolsisteme (bv. toilette) weggooi nie.

HOU ALLE MEDISYNE BUITE BEREIK EN SIG VAN KINDERS.

AANBIEDING VAN SINUFIX FORTE:

Stulpstrokke van 10 kapsules elk, verpak in 'n buitenste karton wat 20 kapsules bevat.

IDENTIFIKASIE VAN SINUFIX FORTE:

Harde, liggroen, grootte 0 kapsule, wat 'n ligbruinerige groen fyn poeier bevat.

REGISTRASIE-NOMMER:

Sal toegeken word.

NAAM EN BESIGHEIDSAADRES VAN DIE

REGISTRASIEHOUDER:

LAMAR INTERNATIONAL (EDMS) BPK

Posbus 4972

Tygervallei

7530

E-pos: info@lamar.co.za

DATUM VAN PUBLIKASIE VAN HIERDIE

PASIËNTINLIGTINGSBLAD:

Junie 2016.

PATIENT INFORMATION LEAFLET

Information for the Patient about

SINUFIX FORTE

Read all of this leaflet carefully before you start using SINUFIX FORTE, because it contains important information for you.

This product is available without a doctor's prescription. Nevertheless you still need to use SINUFIX FORTE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- You must see a doctor if your symptoms worsen or do not improve.
- Do not share SINUFIX FORTE with any other person.
- This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.

SCHEDULING STATUS:

Not scheduled.

PROPRIETARY NAME: (AND DOSAGE FORM):

SINUFIX FORTE
(Hard gelatine capsules)

PHARMACOLOGICAL CLASSIFICATION:

D 5.8 Preparations for the common cold including nasal decongestants

WHAT SINUFIX FORTE CONTAINS:

Each SINUFIX FORTE capsule contains:

Ingredient	Quantity
Gentian (<i>Gentiana lutea</i>) root	12 mg
Primula (<i>Primula veris</i>) flower with calyx	36 mg
Common Sorrel (<i>Rumex acetosa</i>) herb	36 mg
Elder (<i>Sambucus nigra</i>) flowers	36 mg
Verbena (<i>Verbena officinalis</i>) herb	36 mg

Inactive ingredients include dicalcium phosphate, magnesium stearate, starch and Tokusil® (precipitated silica).

SINUFIX FORTE is encapsulated in halaal-certified gelatine. It is free from artificial flavourants and colourants, caffeine, gluten, lactose, preservatives, tartrazine and added yeast.

WHAT SINUFIX FORTE IS USED FOR:

SINUFIX FORTE is an herbal preparation to relieve the symptoms of mild upper respiratory tract infections and sinus pain. It acts by hydrating the sinuses and restoring normal sinus function. It also improves airflow of the nasal passages and sinuses by assisting with the clearance of mucus from the nose and sinuses. SINUFIX FORTE may also relieve symptoms associated with the inflammation of the sinuses and upper respiratory tract.

BEFORE YOU TAKE SINUFIX FORTE:

Do NOT take SINUFIX FORTE:

- If you are allergic (hypersensitive) to any of the active or inactive ingredients in the formulation.
- If you are pregnant or breastfeeding your baby (see "Pregnancy and breastfeeding").
- SINUFIX FORTE should not be used by children younger than 12 years old. Children younger than 12 can use the liquid form (SINUFIX SYRUP).

Take special care with SINUFIX FORTE:

SINUFIX FORTE should not be used to replace any medicines prescribed by your doctor.

Check with your doctor if you are taking prescription medicines (see "Taking other medicines with SINUFIX FORTE").

Please discuss the use of SINUFIX FORTE with your doctor if you:

- Have been diagnosed with any of the following conditions:
 - o Low blood pressure, as gentian might worsen your low blood pressure or interfere with therapy to increase blood pressure.
 - o High or low blood pressure, as high dosages of SINUFIX FORTE may interfere with the control of these conditions.
 - o Stomach ulcer.
 - o Gastrointestinal tract disorders, which includes gastritis, inflammation of the colon, etc.
 - o Kidney disease, especially kidney stones, as large amounts of common sorrel (*Rumex acetosa*) might increase the risk of kidney stones.
 - o Autoimmune disease, as elder (*Sambucus nigra*) flowers might stimulate autoimmune disease activity.
- Are scheduled for surgery. Remember to inform your doctor or anaesthetist that you are taking SINUFIX FORTE.
- Are scheduled to have blood tests done. Remember to inform your healthcare professional that you are taking SINUFIX FORTE.

DO NOT TAKE any other nutritional or herbal supplements without first discussing their combined use with SINUFIX FORTE with your doctor or pharmacist (see "Taking SINUFIX FORTE with other medicines").

Ensure that you stay within the recommended dosage guidelines.

Taking SINUFIX FORTE with food and drink:

SINUFIX FORTE can be taken with or without food.

Pregnancy and breastfeeding:

Do NOT take SINUFIX FORTE while you are pregnant or breastfeeding your baby as safety has not been established (see "Do NOT take SINUFIX FORTE"). SINUFIX FORTE may only be used if you are pregnant or breastfeeding after your doctor has evaluated all the risks involved, and still feels that it would be beneficial to your health.

If you are pregnant or breastfeeding your baby while taking SINUFIX FORTE, please consult your doctor or pharmacist or other healthcare professional for advice.

Driving or using machinery:

It is unlikely that SINUFIX FORTE will affect your ability to drive or operate machines.

However, if you develop side-effects such as dizziness, light-headedness or blurred vision, you should avoid driving a car or operating machinery.

Taking SINUFIX FORTE with other medicines:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of SINUFIX FORTE with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Please discuss the use of the following medicines or substances in combination with SINUFIX FORTE with your doctor or pharmacist:

- Blood pressure lowering supplements or medication, such as: captopril, enalapril, losartan, valsartan, diltiazem, amlodipine, hydrochlorothiazide, furosemide and many others, as this may increase the blood pressure lowering effect.
- Calcium, iron and zinc, as the simultaneous use with sorrel (*Rumex acetosa*) may decrease the absorption of these minerals from the gastrointestinal tract.
- Immunosuppressant drugs, including azathioprine, basiliximab, cyclosporine, daclizumab, muromona-CD3, mycophenolate, tacrolimus, sirolimus, prednisone and any other corticosteroids, as elder (*Sambucus nigra*) may interfere with immunosuppressant therapy because of its immunostimulating activity.
- Tobacco smoking should be discontinued during the use of SINUFIX FORTE as it lowers the effectiveness of the treatment.

HOW TO TAKE SINUFIX FORTE:

Take 1 (one) capsule 3 (three) times per day with a glass of water before, or after, a meal, or as directed by your doctor.

DO NOT EXCEED THE RECOMMENDED DAILY DOSAGE.

SINUFIX FORTE should not be taken for more than 7 – 14 days. If your symptoms last longer than 7 – 14 days or return after the use of SINUFIX FORTE, you should consult your doctor.

Consult your doctor if symptoms persist or if accompanied by a rise in body temperature (fever).

If you have the impression that the effect of SINUFIX FORTE is too strong or too weak, please speak to your doctor or pharmacist.

If you take more SINUFIX FORTE than you should:

If you take more SINUFIX FORTE than you should, you may experience an increase in the side-effects listed below (see "POSSIBLE SIDE-EFFECTS").

In the event of overdose, consult your doctor or pharmacist. If neither is available, immediately seek help at the nearest hospital or poison control centre.

No case of overdosing due to SINUFIX FORTE capsules have been reported to date.

If you forget to take SINUFIX FORTE:

Always take SINUFIX FORTE as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule of one capsule three times per day. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:

SINUFIX FORTE may have side-effects.

Not all side-effects reported for SINUFIX FORTE are included in this leaflet. Should your general health worsen while taking SINUFIX FORTE, please consult your doctor, pharmacist or other healthcare professional for advice.

Side-effects that may occur include:

- Gastrointestinal disturbances, including nausea, vomiting, diarrhoea or stomach ache.
- Allergic skin reactions, including extensive itching and redness.
- Weakness, dizziness and numbness.
- Runny nose and shortness of breath.
- Allergic reactions such as swelling of the skin and face.

Please inform your doctor or pharmacist if you notice any side-effects not mentioned in this leaflet.

STORAGE AND DISPOSING OF SINUFIX FORTE:

Store at or below 25 °C.

Protect from heat and light.

Do not take the capsules after the expiry date stated on the package.

Return all unused capsules to your pharmacist.

Keep the blisters in the outer carton until required for use.

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

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

PRESENTATION OF SINUFIX FORTE:

Blister packs of 10 capsules each packed in an outer carton containing 20 capsules.

IDENTIFICATION OF SINUFIX FORTE:

Hard, light green size 0 capsule containing a light brownish green fine powder.

REGISTRATION NUMBER:

To be allocated.

NAME AND BUSINESS ADDRESS OF THE REGISTRATION

HOLDER:

LAMAR INTERNATIONAL (PTY) LTD

P.O. Box 4972

Tygervalley

7530

Email: info@lamar.co.za

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:

June 2016.