PATIENT INFORMATION LEAFLET
Information for the Patient about
SINUFIX

Read all of this leaflet carefully before you start using SINUFIX, because it contains important information for you.
This product is available without a doctor's prescription. Nevertheless you still need to use SINUFIX 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 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 (Syrup)

PHARMACOLOGICAL CLASSIFICATION:
D 5.8 Preparations for the common cold including nasal decongestants

WHAT SINUFIX CONTAINS:
Each 1 ml of **SINUFIX** syrup contains:

Ingredient	Quantity (mg per 1.0 ml)
Gentian *(Gentiana lutea)* root tincture (1:11, extracting agent 59 % (v/v) ethanol)	9,3 mg
Primula *(Primula veris)* flower with calyx tincture (1:11, extracting agent 59 % (v/v) ethanol)	27,7 mg
Common Sorrel *(Rumex acetosa)* herb tincture (1:11, extracting agent 59 % (v/v) ethanol)	27,7 mg
Elder *(Sambucus nigra)* flowers tincture (1:11, extracting agent 59 % (v/v) ethanol)	27,7 mg
Verbena *(Verbena officinalis)* herb tincture (1:11, extracting agent 59 % (v/v) ethanol)	27,7 mg
Preservatives:	
Potassium sorbate	0,035 % (m/v)
Sodium benzoate	0,045 % (m/v)
Contains alcohol 7,0 % (v/v)	

Inactive ingredients include citric acid, flavouring agent (cherry flavour), sorbitol and water.
Each 1 ml of **SINUFIX** contains 0,38 g sorbitol.
SINUFIX is free from caffeine, tartrazine, artificial colourants, artificial flavourants, gluten, lactose and added yeast. **SINUFIX** contains a nature identical flavourant.

WHAT SINUFIX IS USED FOR:
SINUFIX is a cherry flavoured preparation for adults and children 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 may also relieve symptoms associated with the inflammation of the sinuses and upper respiratory tract.

BEFORE YOU TAKE SINUFIX:
Do NOT take SINUFIX:
- 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"**).

Do NOT administer **SINUFIX** to children aged 2 years or younger, because the safety and efficacy have not been established.

Take special care with SINUFIX:
SINUFIX 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"**).

Please discuss the use of **SINUFIX** 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** 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**.
- Are scheduled to have blood tests done. Remember to inform your healthcare professional that you are taking **SINUFIX**.

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

Ensure that you stay within the recommended dosage guidelines.

Taking SINUFIX with food and drink:
SINUFIX can be taken with or without food.

Pregnancy and breastfeeding:
Do NOT take **SINUFIX** while you are pregnant or breastfeeding your baby as safety has not been established (see **"Do NOT take SINUFIX"**).
SINUFIX 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, please consult your doctor or pharmacist or other healthcare professional for advice.

Driving or using machinery:
It is unlikely that **SINUFIX** will affect your ability to drive or operate machinery.
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 with other medicines:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of SINUFIX 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** 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, muromonab-CD3, mycophenolate, tacrolimus, sirolimus, prednisone and any other corticosteroids, as elder *(Sambucus nigra)* may interfere with immunosuppressant therapy because of its immune-stimulating activity.
- Tobacco smoking should be discontinued during the use of **SINUFIX** as it lowers the effectiveness of the treatment.

HOW TO TAKE SINUFIX:

AGE	DOSAGE INSTRUCTIONS	MAXIMUM DAILY DOSE	QUANTITY SORBITOL / MAXIMUM DAILY DOSE
Children aged 2 to 5 years.	Take 2,1 ml three times daily.	**Do not exceed 6,3 ml.**	2,39 g sorbitol / 6,3 ml
Children aged 6 to 11 years.	Take 3,5 ml three times daily.	**Do not exceed 10,5 ml.**	3,99 g sorbitol / 10,5 ml
Adults and children from the age of 12 years.	Take 7 ml three times daily.	**Do not exceed 21,0 ml.**	7,98 g sorbitol / 21,0 ml

A clear plastic measuring cup is included in the outer carton.
DO NOT EXCEED THE RECOMMENDED DAILY DOSAGE.
SINUFIX can be taken undiluted or mixed with a little water.
Shake well before use.

SINUFIX 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**, you should consult with 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** is too strong or too weak, please speak to your doctor or pharmacist.

If you take more SINUFIX than you should:
If you take more **SINUFIX** than you should, you may experience an increase in the side-effects listed below (see **"POSSIBLE SIDE-EFFECTS"**).
In the event of overdosage, 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** has been reported to date.

If you forget to take SINUFIX:
Always take **SINUFIX** 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 as per dosage instruction (see **"HOW TO TAKE SINUFIX"**). Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:
SINUFIX may have side-effects.
Not all side-effects reported for SINUFIX are included in this leaflet. Should your general health worsen while taking SINUFIX, 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.

SINUFIX may have a laxative effect, as it contains sorbitol.
Please inform your doctor or pharmacist if you notice any side-effects not mentioned in this leaflet.

STORAGE AND DISPOSING OF SINUFIX:
Store at or below 25 °C in a dry place.
Protect from heat and light.
Keep the container tightly closed.
Do not take the syrup after the expiry date stated on the package.
Return all unused syrup to your pharmacist.
Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).
KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

PRESENTATION OF SINUFIX:
100 ml glass amber bottle, with a slow flow dropper bottle cap, packed in an outer carton. A clear plastic measuring cup is included.

IDENTIFICATION OF SINUFIX:
SINUFIX is a yellow to brown syrup with a cherry flavor.

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

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PASIËNTINLIGTINGSBLAD
Inligting vir die Pasiënt rakende
SINUFIX

Lees die hele inligtingsblad deeglik voordat u begin om SINUFIX 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 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 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.**

SKEDULERINGSTATUS:
Ongeskeduleerd.

EIENDOMSNAAM (EN DOSEERVORM):
SINUFIX (Stroop)

FARMAKOLOGIESE KLASSIFIKASIE:
D 5.8 Middels vir verkoue, insluitende nasale ontstuwingsmiddels

WAT SINUFIX BEVAT:
Elke 1 ml **SINUFIX** stroop bevat:

Bestanddeel	Hoeveelheid (mg per 1,0 ml)
Geel gentiaan *(Gentiana lutea)* worteltinktuur (1:11, ekstraheermiddel 59 % (v/v) etanol)	9,3 mg
Primula *(Primula veris)* blom- en kelktinktuur (1:11, ekstraheermiddel 59 % (v/v) etanol)	27,7 mg
Boksuring *(Rumex acetosa)* kruietinktuur (1:11, ekstraheermiddel 59 % (v/v) etanol)	27,7 mg
Europese vlier *(Sambucus nigra)* blomtinktuur (1:11, ekstraheermiddel 59 % (v/v) etanol)	27,7 mg
Ysterkruid *(Verbena officinalis)* kruietinktuur (1:11, ekstraheermiddel 59 % (v/v) etanol)	27,7 mg
Preserveermiddels:	
Kaliumsorbaat	0,035 % (m/v)
Natriumbensoaat	0,045 % (m/v)
Bevat alkohol 7,0 % (v/v)	

Onaktiewe bestanddele sluit in sitroensuur, geurmiddel (kersiegeur), sorbitol en water.
Elke 1 ml **SINUFIX** bevat 0,38 g sorbitol.
SINUFIX bevat nie kafeïen, tartrasien, kunsmatige kleur- en geurmiddels, gluten, laktose en bygevoegde gis nie. **SINUFIX** bevat 'n geurmiddel identies aan die natuurlike een.

WAARVOOR SINUFIX GEBRUIK WORD:
SINUFIX is 'n kersiegeurige preparaat vir volwassenes en kinders om die simptome van ligte boonste lugweginfeksies en sinuspyn 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 mag ook simptome verlig wat verband hou met die ontsteking van die sinusse en boonste lugweg.

VOORDAT U SINUFIX NEEM:
Moet NIE SINUFIX neem NIE:
- Indien u allergies (hipersensitief) is vir enige van die aktiewe of onaktiewe bestanddele in die formulasie.
- Indien u swanger is of u baba borsvoed (sien **"Swangerskap en borsvoeding"**).

Moet NIE **SINUFIX** toedien aan kinders wat 2 jaar of jonger is nie, want die veiligheid en effektiwiteit daarvan is nie bepaal nie.

Neem spesiale sorg met SINUFIX:
SINUFIX moet nie gebruik word om enige medisyne wat deur u dokter voorgeskryf is, te vervang nie.
Kontroleer met u dokter indien u voorskrifmedisyne neem (sien **"Die neem van SINUFIX saam met ander medisyne"**).

Bespreek asseblief die gebruik van **SINUFIX** met u dokter indien u:
- Met enige van die volgende toestande gediagnoseer 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** 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 boksuring *(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** neem.
- Geskeduleer is om bloedtoetse te laat doen. Onthou om u professionele gesondheidsorgwerker in te lig dat u **SINUFIX** neem.

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

Verseker dat u binne die aanbevole doseringsriglyne bly.

Die neem van SINUFIX met kos en drinkgoed:
SINUFIX kan met of sonder kos geneem word.

Swangerskap en borsvoeding:
Moet NIE **SINUFIX** neem terwyl u swanger is of u baba borsvoed nie, aangesien die veiligheid nie bepaal is nie (sien **"Moet NIE SINUFIX neem NIE"**). **SINUFIX** 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 geneem word, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker.

Bestuur en die gebruik van masjinerie:
Dit is onwaarskynlik dat **SINUFIX** u vermoë om te bestuur of masjinerie te hanteer, sal beïnvloed.
Indien u egter newe-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 saam met ander medisyne:

Indien u ander medisyne op 'n gereelde grondslag neem, insluitend komplementêre of tradisionele medisyne, mag die gebruik van SINUFIX 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** met u dokter of apteker:
- Bloeddrukverlagende aanvullings of medikasie, soos: kaptopriel, enalapriel, losartaan, valsartaan, diltiasem, amlodipien, hidrochloortiasied, furosemied en vele ander, aangesien dit die bloeddrukverlagende effek mag versterk.
- Kalsium, yster en sink, aangesien die gelyktydige gebruik saam met boksuring *(Rumex acetosa)* die absorpsie van hierdie minerale uit die gastro-intestinale weg mag verlaag
- Immuunonderdrukkende middels, insluitend asatioprien, basiliksimab, siklosporien, daklisumab, muromonab-CD3, mikofenolaat, takrolimus, sirolimus, prednisoon en enige ander kortikosteroïede, aangesien vlier *(Sambucus nigra)* mag inmeng met immuunonderdrukkerterapie weens die immuunstimulerende aktiwiteit daarvan.
- Die rook van tabak moet gestaak word tydens die gebruik van **SINUFIX** aangesien dit die effektiwiteit van die behandeling verminder.

HOE OM SINUFIX TE NEEM:

OUDERDOM	DOSERINGS-INSTRUKSIES	MAKSIMUM DAAGLIKSE DOSIS	HOEVEELHEID SORBITOL / MAKSIMUM DAAGLIKSE DOSIS
Kinders 2 tot 5-jarige ouderdom.	Neem 2,1 ml drie keer per dag.	**Moenie 6,3 ml oorskry nie.**	2,39 g sorbitol / 6,3 ml
Kinders 6 tot 11-jarige ouderdom.	Neem 3,5 ml drie keer per dag.	**Moenie 10,5 ml oorskry nie.**	3,99 g sorbitol / 10,5 ml
Volwassenes en kinders vanaf 12-jarige ouderdom.	Neem 7 ml drie keer per dag.	**Moenie 21,0 ml oorskry nie.**	7,98 g sorbitol / 21,0 ml

'n Helder plastiekmaatbekertjie is verpak in die buitenste karton.
MOET NIE DIE AANBEVOLE DAAGLIKSE DOSIS OORSKRY NIE.
SINUFIX kan onverdun, of met 'n bietjie water gemeng, geneem word.
Skud bottel deeglik voor gebruik.

SINUFIX moenie 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**, 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** te sterk of te swak is, praat asseblief met u dokter of apteker.

Indien u meer SINUFIX neem as wat u behoort:
Indien u meer **SINUFIX** neem as wat u behoort, mag u 'n toename in die newe-effekte wat hier onder gelys is ervaar (sien **"MOONTLIKE NEWE-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** aangemeld nie.

Indien u vergeet om SINUFIX te neem:
Neem **SINUFIX** altyd soos aangedui. Indien u 'n dosis oorslaan, 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, soos aangedui in die doseringsinstruksies (sien **"HOE OM SINUFIX TE NEEM"**). Moet nie 'n dubbele dosis neem om te vergoed vir die vergete individuele dosisse nie.

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

Newe-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.

SINUFIX mag 'n uitwerking as lakseermiddel hê, omdat dit sorbitol bevat.
Raadpleeg u dokter of apteker indien u enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie.

BERGING EN WEGDOENING VAN SINUFIX:
Bêre by of benede 25 °C in 'n droë plek.
Beskerm teen hitte en lig.
Hou die houer dig toe.
Moenie die stroop ná die vervaldatum op die verpakking neem nie.
Neem al die ongebruikte stroop terug na u apteker.
Moenie ongebruikte medisyne in dreine of rioolsisteme (bv. toilette) weggooi nie.
HOU ALLE MEDISYNE BUITE BEREIK EN SIG VAN KINDERS.

AANBIEDING VAN SINUFIX:
100 ml glas amber bottel, met 'n stadige vloei drupbottelproppie, verpak in 'n buitenste karton. 'n Helder plastiekmaatbekertjie word ingesluit.

IDENTIFIKASIE VAN SINUFIX:
SINUFIX is 'n geel tot bruin stroop met 'n kersiegeur.

REGISTRASIENOMMER:
Sal toegeken word.

NAAM EN BESIGHEIDSADRES VAN DIE REGISTRASIEHOUER:
LAMAR INTERNATIONAL (EDMS) BPK
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