PATIENT INFORMATION LEAFLET FOR SINULEX® FORTE SYRUP

SCHEDULING STATUS
S0

SINULEX® FORTE SYRUP, syrup

Primula veris L. (cowslip), *Rumex acetosa* L. (field sorrel), *Sambucus nigra* L. (elderflower), *Verbena officinalis* L. (verbena), *Gentiana lutea* L. (yellow gentian).
Preservatives: Potassium sorbate 0,035 % *m/v*, sodium benzoate 0,045 % *m/v*.
Contains sweetener: Each 5 ml contains 2 716,65 mg sorbitol.

COMPLEMENTARY MEDICINE: D33.6 WESTERN HERBAL MEDICINE
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 SYRUP is available without a doctor's prescription, for you to maintain your and your child's health. Nevertheless, you still need to use or give SINULEX® FORTE SYRUP 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, or your child's symptoms worsen or do not improve after 10 days.

What is in this leaflet

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

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

SINULEX® FORTE SYRUP may assist in:

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

2. What you need to know before you or your child take SINULEX® FORTE SYRUP

Do not use or give SINULEX® FORTE SYRUP:

- if your child is under the age of 2 years;
- if you or your child is hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of SINULEX® FORTE SYRUP (see **What SINULEX® FORTE SYRUP contains**);
- if you or your child suffers from diabetes mellitus type 1 and type 2;
- if you or your child has liver disease or problems;
- 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 providers for advice before taking SINULEX® FORTE SYRUP.

Warnings and precautions

SINULEX® FORTE SYRUP contains preservatives:

SINULEX® FORTE SYRUP contains potassium sorbate and sodium benzoate, which may cause allergic reactions.

SINULEX® FORTE SYRUP contains sorbitol (E420):

- SINULEX® FORTE SYRUP contains sorbitol.
- If you or your child are taking other products with sorbitol or fructose, or if you or your child eat foods with sorbitol or fructose, caution is advised.
- The sorbitol in medications might change how well other oral medications work when taken together.
- People with hereditary fructose intolerance (HFI) shouldn't use SINULEX® FORTE SYRUP.
- Sorbitol may have a mild laxative effect.

Other medicines and SINULEX® FORTE SYRUP

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

- Caution is advised when taking SINULEX® FORTE SYRUP in conjunction with other medicine for diabetes due to the elderflower content in this medicine.
- The elderflower might cause the diabetes medicine to work for a longer period, or in a stronger way.
- If you or your child are already taking prescription diabetes medicine, it's best to check with your doctor before taking SINULEX® FORTE SYRUP in conjunction with it.

SINULEX® FORTE SYRUP with food, drink and alcohol

See section 3 (**How to use SINULEX® FORTE SYRUP)**.

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 SYRUP.

The safety and efficacy of SINULEX® FORTE SYRUP during pregnancy and breastfeeding have not been established.

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

Driving and using machines

SINULEX® FORTE SYRUP might make you or your child feel drowsy. Do not drive a vehicle, operate machinery, or do anything else that requires your or your child's attention until you know how SINULEX® FORTE SYRUP affects you or your child.

3. How to use SINULEX® FORTE SYRUP or give it to your child

Do not share your or your child's medicines with any other person.

Always use/give your child SINULEX® FORTE SYRUP exactly as described in this leaflet, or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Children 2 – 5 years: 2,5 ml (half a medicine measure) three times per day.

Children 6 – 12 years: 3,75 ml (three-quarters of a medicine measure) three times per day.

Adults and children above 12 years: 7,5 ml (one and a half medicine measure) three times per day.

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

Do not exceed the recommended dosage.

Shake the bottle well before use.

SINULEX® FORTE SYRUP can be taken with or without food.

If you take/give your child more SINULEX® FORTE SYRUP than you should

In the event of overdosage, 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 SYRUP with you so the doctor will know what you or your child have taken.

4. Possible side effects

SINULEX® FORTE SYRUP can have side effects.
Not all side effects reported for SINULEX® FORTE SYRUP are included in this leaflet. Should you or your child's general health worsen or if you or your child experiences any untoward effects while taking SINULEX® FORTE SYRUP, please consult your healthcare provider for advice.

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

- swelling of your or your child's 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 or your child has them, it could indicate a serious allergic reaction to SINULEX® FORTE SYRUP, requiring 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 in yourself or your child:

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

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you or your child get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions 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 SYRUP.

5. How to store SINULEX® FORTE SYRUP

- 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.
- Do not refrigerate or freeze this product.
- Do not use after the expiry date printed on the label.
- Keep the bottle tightly closed.
- 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 SYRUP contains

Each 5 ml contains:
The active substances are:

Primula veris L. (Cowslip)	141,42 mg
[flower, as 1:11 ethanol extract equivalent to 12,85 mg dried herb]	
Rumex acetosa L. (Field sorrel)	141,42 mg
[herb, as 1:11 ethanol extract equivalent to 12,85 mg dried herb]	
Sambucus nigra L. (Elderflower)	141,42 mg
[flower, as 1:11 ethanol extract equivalent to 12,85 mg dried herb]	

Verbena officinalis L. (Verbena)	141,42 mg
[herb, as 1:11 ethanol extract equivalent to 12,85 mg dried herb]	
Gentiana lutea L. (Yellow gentian)	47,14 mg
[root, as 1:11 ethanol extract equivalent to 4,28 mg dried herb]	

The other ingredients are carmellose sodium (E468), citric acid (E330), ethanol, glycerine BP (E422), potassium sorbate (E202), sodium benzoate (E211), sorbitol 70 % (E420), *Tutti Frutti* flavour (CR-048) and water.

What SINULEX® FORTE SYRUP looks like and contents of the pack
100 ml opaque maple coloured syrup with a *Tutti Frutti* flavour in a cap-sealed amber glass bottle. Packed in an outer carton with a patient information leaflet.

Holder of Certificate of Registration
Brunel Laboratoria (Pty) Ltd
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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 SYRUP is available at
https://www.brunel.co.za/professional-information/ or can be requested from the contact details above.

PASIËNTINLIGTINGSBLAD VIR SINULEX® FORTE SYRUP

SKEDULERINGSTATUS
S0

SINULEX® FORTE SYRUP, stroop
Primula veris L. (koeislop), *Rumex acetosa* L. (veldsuring), *Sambucus nigra* L. (vlierblom), *Verbena officinalis* L. (verbena), *Gentiana lutea* L. (geel gentiaan).
Preserveermiddels: Kaliumsorbaat 0,035 % *m/v*, natriumbensoaat 0,045 % *m/v*.
Bevat versoeter: Elke 5 ml bevat 2 716,65 mg sorbitol.

KOMPLEMENTÊRE MEDISYNE: D33.6 WESTERSE KRUIE MEDISYNE
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 SYRUP is beskikbaar sonder 'n dokter se voorskrif, om jou en jou kind se gesondheid te onderhou. Nietemin, moet jy SINULEX® FORTE SYRUP versigtig gebruik of gee 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 spreek indien jou of jou kind se simptome vererger of nie verbeter na 10 dae nie.

Wat is in hierdie inligtingsblad
1. Wat SINULEX® FORTE SYRUP is, en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy of jou kind SINULEX® FORTE SYRUP gebruik.
3. Hoe om SINULEX® FORTE SYRUP te gebruik of vir jou kind te gee.
4. Moontlike newe-effekte.
5. Hoe om SINULEX® FORTE SYRUP te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat SINULEX® FORTE SYRUP is, en waarvoor dit gebruik word
SINULEX® FORTE SYRUP 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 of jou kind SINULEX® FORTE SYRUP gebruik
Moet nie SINULEX® FORTE SYRUP gebruik:
- indien jou kind onder die ouderdom van 2 jaar is nie;
- indien jy of jou kind hipersensitief (allergies) is vir enige van die aktiewe bestanddele of vir enige van die ander bestanddele van SINULEX® FORTE SYRUP nie (sien **SINULEX® FORTE SYRUP bevat**);
- indien jy of jou kind ly aan diabetes mellitus tipe 1 en tipe 2 nie;
- indien jy of jou kind lewersiekte of probleme het nie;
- as jy swanger is of borsvoed, dink jy dat jy swanger kan wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffers vir advies voordat jy SINULEX® FORTE SYRUP inneem.

Waarskuwings en voorsorgmaatreëls
SINULEX® FORTE SYRUP bevat preserveermiddels:
SINULEX® FORTE SYRUP bevat kaliumsorbaat en natriumbensoaat, wat allergiese reaksies kan veroorsaak.

SINULEX® FORTE SYRUP bevat sorbitol (E420):
- SINULEX® FORTE SYRUP bevat sorbitol.
- As jy of jou kind ander produkte met sorbitol of fruktose gebruik, of as jy of jou kind voedsel met sorbitol of fruktose eet, moet jy of jou kind versigtig wees.
- Die sorbitol in medisyne kan moontlik die effektiwiteit van ander orale medisyne verander wanneer dit saam gebruik word.
- Mense met oorerflike fruktose-intoleransie (HFI) moet nie SINULEX® FORTE SYRUP gebruik nie.
- Sorbitol kan 'n ligte lakserende effek hê.

Ander medisyne en SINULEX® FORTE SYRUP
Sê altyd vir jou gesondheidsorgverskaffer indien jy of jou kind enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

- Wees versigtig wanneer SINULEX® FORTE SYRUP saam met ander medisyne vir diabetes geneem word as gevolg van die vlierblom inhoud in hierdie medisyne.
- Die vlierblom mag veroorsaak dat die diabetesmedisyne vir langer of op 'n sterker manier werk.
- As jy of jou kind reeds voorgeskrewe diabetesmedisyne neem, is dit belangrik om dit met jou dokter te bespreek voordat jy of jou kind SINULEX® FORTE SYRUP saam met dit gebruik.

SINULEX® FORTE SYRUP met eet- , drinkgoed of alkohol
Sien afdeling 3 (**Hoe om SINULEX® FORTE SYRUP te gebruik**).

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 SYRUP neem.
Die veiligheid en effektiwiteit van SINULEX® FORTE SYRUP tydens swangerskap en borsvoeding is nie vasgestel nie.

Bestuur en die gebruik van masjiene
SINULEX® FORTE SYRUP mag jou of jou kind dalk slaperig laat voel. Moet nie 'n voertuig bestuur, masjinerie bedryf, of enige iets anders doen wat jou of jou kind se aandag vereis nie totdat jy weet hoe SINULEX® FORTE STROOP jou of jou kind affekteer nie.

3. Hoe om SINULEX® FORTE SYRUP te gebruik of vir jou kind te gee
Moet nie jou of jou kind se medisyne met enige ander persoon deel nie.
Gebruik SINULEX® FORTE SYRUP altyd presies soos wat in hierdie inligtingsblad beskryf word, of soos wat jou dokter of apteker vir jou gesê het. Vra gerus jou dokter of apteker indien jy onseker is.
Die gewone dosis is:
Kinders 2 – 5 jarige ouderdom: 2,5 ml (halwe medisyne maat) drie keer per dag.
Kinders 6 – 12 jarige ouderdom: 3,75 ml (driekwart medisyne maat) drie keer per dag.
Volwassenes en kinders bo 12 jarige ouderdom: 7,5 ml (een en ‘n halwe medisyne maat) drie keer per dag.

Indien jy die indruk kry dat die uitwerking van SINULEX® FORTE SYRUP te sterk of te swak is, bespreek dit met jou dokter of apteker.

Moet nie die aanbevole dosis oorskry nie.
Skud die bottel goed voor gebruik.
SINULEX® FORTE SYRUP kan met of sonder kos geneem word.

As jy meer SINULEX® FORTE SYRUP ingeneem het of vir jou kind gegee het 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 SYRUP saam met jou sodat die dokter kan sien wat jy of jou kind ingeneem het.

4. Moontlike newe-effekte

SINULEX® FORTE SYRUP kan newe-effekte hê.
Nie alle newe-effekte wat vir SINULEX® FORTE SYRUP gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou of jou kind se algemene gesondheid verswak of jy of jou kind enige ongunstige effekte ondervind terwyl SINULEX® FORTE SYRUP geneem word, raadpleeg asseblief jou gesondheidsorgverskaffer.

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

- swelling van jou of jou kind se 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 of jou kind enige daarvan ondervind, mag jy of jou kind ’n ernstige allergiese reaksie op SINULEX® FORTE SYRUP gehad het. Dringende mediese bystand of hospitalisasie mag nodig wees.

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

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

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

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 of jou kind enige newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die “**6.04 Adverse Drug Reactions 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 SYRUP te verskaf.

5. Hoe om SINULEX® FORTE SYRUP te bêre

- Bêre alle medisyne buite die bereik van kinders.
- Bêre teen of onder 25 ºC in ‘n koel, droë plek, en beskerm teen lig.
- Moet nie in die badkamer bêre nie.
- Moet nie hierdie produk in die yskas of vrieskas bêre nie.
- Moet nie gebruik word na die vervaldatum wat op die etiket gedruk is nie.
- Hou die bottel dig toe.
- 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 SYRUP bevat

Elke 5 ml bevat:
Die aktiewe bestanddele is:

Primula veris L. (Koeislop) .... 141,42 mg
[blom, 1:11 etanol-ekstrak lewer 12,85 mg gedroogde kruie ekwivalent]
Rumex acetosa L. (Veldsuring) .... 141,42 mg
[krui, 1:11 etanol-ekstrak lewer 12,85 mg gedroogde kruie ekwivalent]
Sambucus nigra L. (Vlierblom) .... 141,42 mg
[blom, 1:11 etanol-ekstrak lewer 12,85 mg gedroogde kruie ekwivalent]
Verbena officinalis L. (Verbena) .... 141,42 mg
[krui, 1:11 etanol-ekstrak lewer 12,85 mg gedroogde kruie ekwivalent]

Gentiana lutea L. (Geel gentiaan) .... 47,14 mg
[wortel, 1:11 etanol-ekstrak lewer 4,28 mg gedroogde kruie ekwivalent]

Die ander bestanddele is karmellose natrium (E468), sitroensuur (E330), etanol, gliserien BP (E422), kaliumsorbaat (E202), natriumbensoaat (E211), sorbitol 70% (E420), *Tutti Frutti*-geursel (CR-048) en water.

Hoe SINULEX® FORTE SYRUP lyk en die inhoud van die verpakking
100 ml stroop met ‘n ligbruin skynsel en ‘n *Tutti Frutti*-geur in 'n dop-verseëlde amberglasbottel. Verpak in 'n buitenste karton wat 'n pasiëntinligtingsblad bevat.

Houer van die Registrasiesertifikaat
Brunel Laboratoria (Edms) Bpk
Van Tonderstraat 1
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Hierdie inligtingsblad is hersien in
Sal met registrasie deur SAHPRA aangedui word.

Registrasienommer
Sal met registrasie deur SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad
Die Professionele Inligtingsblad vir SINULEX® FORTE SYRUP 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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