PATIENT INFORMATION LEAFLET FOR SINULEX® FORTE FIZZY

SCHEDULING STATUS
S0

SINULEX® FORTE FIZZY, effervescent tablets
L-Ascorbic acid (vitamin C), *Echinacea purpurea* (L.) Moench (echinacea),
Armoracia rusticana G. Gaertn. (horseradish), zinc gluconate,
riboflavin (vitamin B_2), cholecalciferol (vitamin D_3).
Contains sugar alcohol: Each effervescent tablet contains 1 400 mg isomalt (E953).
Contains sweetener: Each effervescent tablet contains 6,6 mg sucralose (E955)
and 3,4 mg acesulfame K (E950).

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT
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 FIZZY is available without a doctor's prescription, for you to maintain your health.
Nevertheless, you still need to use SINULEX® FORTE FIZZY 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 symptoms worsen or do not improve after 10 days.

What is in this leaflet
1. What SINULEX® FORTE FIZZY is and what it is used for.
2. What you need to know before you take SINULEX® FORTE FIZZY.
3. How to take SINULEX® FORTE FIZZY.
4. Possible side effects.
5. How to store SINULEX® FORTE FIZZY.
6. Contents of the pack and other information.

1. What SINULEX® FORTE FIZZY is and what it is used for
SINULEX® FORTE FIZZY is a soothing drink that may assist in:
- maintaining a healthy respiratory system;
- enhancing the body's natural defense mechanisms;
- strengthening the immune system;
- combatting seasonal allergies, colds, flu, and sinusitis;
- enhancing airway functionality.

2. What you need to know before you take SINULEX® FORTE FIZZY
Do not take SINULEX® FORTE FIZZY:
- if you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients of SINULEX® FORTE FIZZY (see **What SINULEX® FORTE FIZZY contains**).

Warnings and precautions
Take special care with SINULEX® FORTE FIZZY:
- if you have autoimmune diseases or using prescription immunosuppressants. This medicine has immunostimulant effects; avoid use.

Other medicines and SINULEX® FORTE FIZZY
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently using:
- immunosuppressants (used to treat autoimmune diseases).

SINULEX® FORTE FIZZY with food, drink and alcohol
See section 3 (**How to take SINULEX® FORTE FIZZY**).

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 FIZZY.
Safety and efficacy of SINULEX® FORTE FIZZY during pregnancy and breastfeeding have not been established. Do not use SINULEX® FORTE FIZZY if you are pregnant or breastfeeding your baby.

Driving and using machines
Safety and efficacy when driving or operating machinery have not been established. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how SINULEX® FORTE FIZZY affects you.

SINULEX® FORTE FIZZY contains isomalt (E953)
SINULEX® FORTE FIZZY contains 1 400 mg isomalt in each effervescent tablet.
Isomalt may have a mild laxative effect.

SINULEX® FORTE FIZZY contains sucralose (E955)
SINULEX® FORTE FIZZY contains 6,6 mg sucralose in each effervescent tablet.
When you are using products that contain sucralose and eating foods with sucralose, it's important to note how they might affect each other. If you are taking any oral medications that contains sucralose, they could change how other oral medications work when you take them at the same time.

3. How to take SINULEX® FORTE FIZZY

Do not share your medicines with any other person.
Always take SINULEX® FORTE FIZZY exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The usual dose is:
Acute Dosage:
Adults and children above the age of 12 years: Dissolve 1 tablet in 200 ml room temperature water three times a day.
Children 6 – 12 years: Dissolve half a tablet in 200 ml room temperature water three times a day.
It is recommended to take this dosage for at least 5 consecutive days.

Maintenance Dosage:
Adults and children above the age of 12 years: Dissolve 1 tablet in 200 ml room temperature water once daily.
Children 6 – 12 years: Dissolve half a tablet in 200 ml room temperature water once daily.

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

Dosages as per above or as prescribed by a healthcare professional.
Do not exceed the recommended dosage.
SINULEX® FORTE FIZZY should be taken after meals.

If you take more SINULEX® FORTE FIZZY than you should
In the event of an 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 FIZZY with you so the doctor will know what you have taken.

4. Possible side effects

SINULEX® FORTE FIZZY can have side effects.

Not all side effects reported for SINULEX® FORTE FIZZY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SINULEX® FORTE FIZZY, please consult your healthcare provider for advice.

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

- swelling of your 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 have them, you may have had a serious allergic reaction to SINULEX® FORTE FIZZY. You may need 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:

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

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

Tell your doctor if you notice any of the following:
Side effects occurring with an unknown frequency:

- headache;
- flushing (face becomes red and hot);
- nausea (feeling sick);
- vomiting (being sick);
- stomach cramps;
- diarrhoea (runny, loose stools);
- discomforts of the gastrointestinal tract;
- hyperoxaluria (too much oxalate in the urine);
- hypersensitivity reaction;
- metallic taste;
- mouth irritation;
- dry mouth;
- hypercalcaemia (too much calcium in the blood);
- hypercalciuria (too much calcium in the urine);
- pruritus (itching);
- rash;
- urticaria (hives).

Side effects occurring with a rare frequency:

- diarrhoea (runny, loose stools);
- polyuria (urinating more often and/or producing larger amounts of urine than usual);
- chromaturia (abnormal colours in the urine).

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

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**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 SINULEX® FORTE FIZZY.

5. How to store SINULEX® FORTE FIZZY

- 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.
- Keep the container tightly closed.
- Do not refrigerate or freeze this product.
- Do not use after the expiry date stated on the carton or container.
- 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 FIZZY contains

Each effervescent tablet contains:
The active substances are:

L-Ascorbic acid (Vitamin C)…………..	300 mg
Echinacea purpurea (L.) Moench (Echinacea)……..………………….	125 mg
[root, 4:1 extract equivalent to 500 mg dried herb]	
Armoracia rusticana G. Gaertn. (Horseradish)………………………...	50 mg
[root, 4:1 extract equivalent to 200 mg dried herb]	
Zinc gluconate……………………………………………………………..	16,7 mg
providing Zinc (elemental)……………………………………………	2 mg
Riboflavin (Vitamin B_2)…………………………………………………	2 mg
Cholecalciferol (Vitamin D_3)……………………………………………..	333 I.U. (8,33 µg)

The other ingredients are acesulfame K (E950), citric acid (E330), GalenIQ 721, isomalt (E953), kollidon CL, orange flavouring, povidone K25, powder lipoxol PEG 6000, silicon dioxide (E551), sodium bicarbonate (E500), sucralose (E955) and tartaric acid (E334).

What SINULEX® FORTE FIZZY looks like and contents of the pack

Light brown coloured, speckled, flat, round effervescent tablet.
Due to the natural ingredients, the colour of some ingredients may vary from batch to batch.
SINULEX® FORTE FIZZY effervescent tablets are packed in a printed tubular container, placed inside an outer carton with a patient information leaflet.
Pack size: 12 effervescent tablets.

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 FIZZY is available on
https://www.brunel.co.za/professional-information/ or can be requested from the contact details above.

PASIËNTINLIGTINGSBLAD VIR SINULEX® FORTE FIZZY

SKEDULERINGSTATUS
S0

SINULEX® FORTE FIZZY, bruistablette

L-Askorbiensuur (vitamien C), *Echinacea purpurea* (L.) Moench (echinacea), *Armoracia rusticana* G. Gaertn. (peperwortel), sinkglukonaat, riboflavien (vitamien B_2), cholekalsiferol (vitamien D_3).
Bevat suiker alkohol: Elke bruistablet bevat 1 400 mg isomalt (E953).
Bevat versoeter: Elke bruistablet bevat 6,6 mg sukralose (E955) and 3,4 mg asesulfaam K (E950).

KOMPLEMENTÊRE MEDISYNE: KOMBINASIEPRODUK
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 FIZZY is beskikbaar sonder 'n dokter se voorskrif, vir jou om jou gesondheid te onderhou. Nietemin, moet jy SINULEX® FORTE FIZZY versigtig gebruik 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 sien as jou simptome vererger of nie verbeter na 10 dae nie.

Wat is in hierdie inligtingsblad

1. Wat SINULEX® FORTE FIZZY is, en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy SINULEX® FORTE FIZZY neem.
3. Hoe om SINULEX® FORTE FIZZY te neem.
4. Moontlike newe-effekte.
5. Hoe om SINULEX® FORTE FIZZY te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat SINULEX® FORTE FIZZY is, en waarvoor dit gebruik word

SINULEX® FORTE FIZZY is 'n strelende drankie wat kan 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 SINULEX® FORTE FIZZY neem

Moet nie SINULEX® FORTE FIZZY neem:

- indien jy hipersensitief (allergies) is vir enige van die aktiewe bestanddele of vir enige van die ander bestanddele van SINULEX® FORTE FIZZY nie (sien **Wat SINULEX® FORTE FIZZY bevat**).

Waarskuwings en voorsorgmaatreëls

Wees versigtig met SINULEX® FORTE FIZZY:

- indien jy 'n outo-immuun siekte het of voorskrif immuunonderdrukkers gebruik. Hierdie medisyne het immunostimulerende effekte; vermy gebruik.

Ander medisyne en SINULEX® FORTE FIZZY

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

Sê vir jou dokter of apteker indien jy tans die volgende gebruik:

- immuunonderdrukkers (gebruik om outo-immuun siektes te behandel).

SINULEX® FORTE FIZZY met eet-, drinkgoed en alkohol
Sien afdeling 3 (**Hoe om SINULEX® FORTE FIZZY te neem**).

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 FIZZY neem.
Dit is nie vasgestel of SINULEX® FORTE FIZZY veilig en doeltreffend is om tydens swangerskap en borsvoeding te gebruik nie.
Moet nie SINULEX® FORTE FIZZY gebruik indien jy swanger is of jou baba borsvoed nie.

Bestuur en die gebruik van masjiene
Dit is nie vasgestel of SINULEX® FORTE FIZZY veilig en doeltreffend is tydens bestuur en die gebruik van masjiene nie. Moet nie 'n voertuig bestuur, masjiene hanteer, of enigiets anders doen wat jou aandag vereis totdat jy weet hoe SINULEX® FORTE FIZZY jou affekteer nie.

SINULEX® FORTE FIZZY bevat isomalt (E953)
SINULEX® FORTE FIZZY bevat 1 400 mg isomalt per bruistablet.
Isomalt kan 'n ligte lakserende effek hê.

SINULEX® FORTE FIZZY bevat sukralose (E955)
SINULEX® FORTE FIZZY bevat 6,6 mg sukralose per bruistablet.
Wanneer jy produkte gebruik wat sukralose bevat en kosse met sukralose eet, is dit belangrik om kennis te neem oor hoe hulle mekaar kan beïnvloed. As jy enige orale medikasie met sukralose in neem, kan dit verander hoe ander orale medikasie werk wanneer jy dit saam neem.

3. Hoe om SINULEX® FORTE FIZZY te neem
Moet nie jou medisyne met enige ander persoon deel nie.
Neem SINULEX® FORTE FIZZY altyd presies soos aangedui in hierdie inligtingsblad, of soos jou dokter of apteker vir jou verduidelik het. Vra gerus vir jou dokter of apteker indien jy onseker is.
Die gewone dosis is:
Akute dosering:
Volwassenes en kinders ouer as 12-jarige ouderdom: Los 1 tablet op in 200 ml kamertemperatuur water drie keer per dag.
Kinders 6 – 12 jaar: Los 'n halwe tablet op in 200 ml kamertemperatuur water drie keer per dag.
Dit word aanbeveel om hierdie dosis vir ten minste 5 opeenvolgende dae te neem.

Onderhoudsdosering:
Volwassenes en kinders ouer as 12-jarige ouderdom: Los 1 tablet op in 200 ml kamertemperatuur water een keer per dag.
Kinders 6 – 12 jaar: Los 'n halwe tablet op in 200 ml kamertemperatuur water een keer per dag.

As jy die indruk kry dat die effek van SINULEX® FORTE FIZZY te sterk of te swak is, vertel jou dokter of apteker.

Doserings soos bo aangedui of soos voorgeskryf deur 'n gesondheidsorgverskaffer.
Moet nie die aanbevole dosis oorskry nie.
SINULEX® FORTE FIZZY moet na etes geneem word.

As jy meer SINULEX® FORTE FIZZY neem 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 FIZZY saam met jou sodat die dokter kan sien wat jy geneem het.

4. Moontlike newe-effekte
SINULEX® FORTE FIZZY kan newe-effekte hê.
Nie alle newe-effekte wat vir SINULEX® FORTE FIZZY gerapporteer is, word in hierdie inligtingsblad ingesluit nie.
Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy

SINULEX® FORTE FIZZY neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

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

- swelling van jou 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 enige daarvan ondervind, mag jy 'n ernstige allergiese reaksie op SINULEX® FORTE FIZZY gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

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

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

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

Sê vir jou dokter indien jy enige van die volgende opmerk:
Newe-effekte wat met 'n onbekende frekwensie voorkom:

- hoofpyn;
- blosing (gesig word rooi en warm);
- naarheid;
- braking;
- maagkrampe;
- diarree (loperige, los stoelgange);
- ongemak van die spysverteringskanaal;
- hiperoksalurie (te veel oksalaat in die urine);
- hipersensitiwiteitsreaksie;
- metaal smaak;
- mond irritasie;
- droë mond;
- hiperkalsemie (te veel kalsium in die bloed);
- hiperkalsiurie (te veel kalsium in die urine);
- pruritus (jeuk);
- uitslag;
- urtikaria (korwe/galbulte).

Newe-effekte wat met 'n seldsame frekwensie voorkom:

- diarree (loperige, los stoelgange);
- poliurie (meer gereeld urinering en/of groter hoeveelhede urine as gewoonlik produseer);
- chromaturie (abnormale kleure in die urine).

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 newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die "**6.04 Adverse Drug Reaction 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 FIZZY te verskaf.

5. Hoe om SINULEX® FORTE FIZZY te bêre

- Bêre alle medisyne buite die bereik van kinders.
- Bêre teen of onder 25 °C, in 'n koel, droë plek, beskerm teen lig.
- Moet nie in die badkamer bêre nie.

- Hou die buisie dig toe.
- Moet nie hierdie produk in die yskas of vrieskas bêre nie.
- Moet nie gebruik na die vervaldatum soos aangedui op die buisie of die boksie nie.
- 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 FIZZY bevat

Elke bruistablet bevat:

Die aktiewe bestanddele is:

L-Askorbiensuur (Vitamien C)…………..	300 mg
Echinacea purpurea (L.) Moench (Echinacea)……..………………….	125 mg
[wortel, 4:1 ekstrak lewer 500 mg gedroogde kruie ekwivalent]	
Armoracia rusticana G. Gaertn. (Peperwortel)………………………..	50 mg
[wortel, 4:1 ekstrak lewer 200 mg gedroogde kruie ekwivalent]	
Sinkglukonaat………………………………………………………………..	16,7 mg
lewer Sink (elementaal)……………………………………………....	2 mg
Riboflavien (Vitamien B_2)………………………………………………..	2 mg
Cholekalsiferol (Vitamien D_3)…………………………………………..	333 I.U. (8,33 µg)

Die ander bestanddele is asesulfaam K (E950), sitroensuur (E330), GalenIQ 721, isomalt (E953), kollidon CL, lemoen geursel, povidoon K25, poeier lipoxol PEG 6000, silikondioksied (E551), natriumbikarbonaat (E500), sukralose (E955) en wynsteensuur (E334).

Hoe SINULEX® FORTE FIZZY lyk en inhoud van die verpakking

Ligbruin, gespikkelde, plat, ronde bruistablet.

Die kleur van sommige bestanddele kan wissel tussen lotte, omdat dit van natuurlike oorsprong is.

SINULEX® FORTE FIZZY word in 'n gedrukte buisvormige houer verpak en binne 'n karton geplaas met 'n pasiëntinligtingsblad.

Verpakkingsgrootte: 12 bruistablette.

Houer van die Registrasiesertifikaat

Brunel Laboratoria (Edms) Bpk
Van Tonderstraat 1
Sunderland Ridge
Centurion
0157
info@brunel.co.za

Hierdie inligtingsblad is hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.

Toegang tot die ooreenstemmende Professionele Inligtingsblad

Die Professionele Inligtingsblad vir SINULEX® FORTE FIZZY is beskikbaar by https://www.brunel.co.za/professional-information/ of dit kan aangevra word deur die kontakbesonderhede hier bo te gebruik.