



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),
A Armoracia rusticana G. Gaertn. (horseradish), zinc gluconate,
riboflavin (vitamin B₂), cholecalciferol (vitamin D₃).

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 overdose, 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
<i>Echinacea purpurea</i> (L.) Moench (Echinacea).....	125 mg
[root, 4:1 extract equivalent to 500 mg dried herb]	
<i>Armoracia rusticana</i> 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

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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.