



## 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:

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

<i>Verbena officinalis</i> L. (Verbena) .....	141,42 mg
[herb, as 1:11 ethanol extract equivalent to 12,85 mg dried herb]	
<i>Gentiana lutea</i> 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  
 1 Van Tonder Street  
 Sunderland Ridge  
 Centurion  
 0157  
[info@brunel.co.za](mailto:info@brunel.co.za)

**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.

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