sinulex FORTE
SINUS, COLDS & FLU SUPPORT
SINUS, VERKOUE & GRIEP ONDERSTEUNING

PROFESSIONAL INFORMATION: CONTENT UNDER EACH HEADING

- This product is a Complementary Medicine (Category D33.7);
- and is identified according to its discipline as a Combination Product;
- which is not registered by the Authority.
- **This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety, or intended use.**

SCHEDULING STATUS:

S0

1. NAME OF THE MEDICINE

Sinulex® Forte Syrup

Strength

- 858 mg per 7 mL; or
- 12 257 mg per 100 mL

Pharmaceutical form

Liquid, syrup, oral

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 7 mL of syrup contains:

Primula veris L. (Cowslip) [Flower, 1:11 extract]	198 mg
Rumex acetosa L. (Field sorrel) [Leaf, 1:11 extract]	198 mg
Sambucus nigra L. (Elderflower) [Flower, 1:11 extract]	198 mg
Verbena officinalis L. (Verbena) [Leaf, 1:11 extract]	198 mg
Gentiana lutea L. (Yellow gentian) [Root, 1:11 extract]	66 mg

Excipients:

- Non-essential to proper administration;
- for a full list of excipients and the amounts of each excipient per 7 mL of syrup, see section 6.1

Sugar-free.
Contains sweetener:

- Sorbitol

3. PHARMACEUTICAL FORM

Liquid, syrup, opaque maple color, pourable viscosity, markings not applicable.

4. CLINICAL PARTICULAR

4.1. Therapeutic indications

- To support the immune system to deal with coughs, allergens, colds, flu, and sinusitis for better overall health.
- Due to the active substances, Sinulex® Forte Syrup is indicated for therapeutic use only from the age of 2 years and older.

- These active substances are useful for symptomatic relief of sinus pressure, sinus congestion, post-nasal drip, colds, and flu symptoms, by supporting the respiratory and immune systems. Its active substances may also support the immune function of those who are asymptomatic as a low-risk health supplement.
- It is a health supplement that contains important expectorant, anti-bacterial, anti-microbial, anti-inflammatory, and sedative properties and can be used to support the respiratory tract, supporting the paranasal sinuses.
- Sinulex® Forte Syrup is indicated for self-administration as a low-risk health supplement, although only a healthcare provider may indicate it as an adjunct treatment to an existing treatment regimen for individual persons.
- It is not indicated as an alternative therapy to replace conventional medicines or any other treatments prescribed by a healthcare provider.
  Sinulex® Forte Syrup is a medicinal health supplement not intended (nor indicated) for maintenance or alternative maintenance therapy, but rather for symptomatic relief when this medicine is needed.

- It is not indicated as a cure-all or monotherapy for serious conditions because Sinulex® Forte Syrup is not intended (nor indicated) to diagnose, treat, prevent, or cure diseases.
- It is strictly indicated for symptomatic relief as a low-risk supportive supplement.

4.2. Posology and method of administration

Posology

Single dose, 858 mg per 7 mL of syrup.

The potency of this medicine is expressed in 7 mL of syrup units. These units are not interchangeable with the units used to express the potency of other preparations that contain the same active substances. No more than the recommended dosage should be taken, and persons should not take or use a double dose to make up for forgotten individual doses.

Adolescents over the age of 12, adults, and the elderly

1½ teaspoon or 7 mL of syrup, 3 times daily, which is the daily equivalent of 3 times a full single dose. This is the maximum recommended daily and/or total dose.

Children above the age of 6 years

¾ teaspoon or 3.5 mL of syrup, 3 times daily, which is the daily equivalent of 1.5 times a full single dose. This is the maximum recommended daily and/or total dose.

Children above the age of 2 years

½ teaspoon or 2.1 mL of syrup, 3 times daily, which is the daily equivalent of 1 full single dose. This is the maximum recommended daily and/or total dose.

Duration of use

If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Method of administration

Oral use only.

4.3. Contraindications

Allergic or hypersensitive to the active substances. Insufficient data is available to establish safety during pregnancy and lactation; avoid use. Because this medicine already has hypoglycemic and sedative properties, those with diabetes or using prescription hypoglycemic drugs may need to avoid using this medicine. Based on an existing treatment regimen or pre-existing condition there may be other contraindications (see section 4.5 ‘Interaction with other medicines and other forms of interaction’).

4.4. Special warnings and precautions

In the absence of sufficient data, the use during pregnancy and lactation is not recommended (see section 4.6 ‘Fertility, pregnancy, and lactation’). Sinulex® Forte Syrup is not established as safe for use in persons younger than 2 years of age. Adequate care must be taken to keep this medicine out of the reach of children.
The maximum recommended daily and/or total dose should not be exceeded. Sinulex® Forte Syrup contains Elderflower and Yellow Gentian that acts as a hypoglycemic agent and sedative, respectively. Because of elderflower and yellow gentian, advise patients with diabetes and may already be on prescription hypoglycemic drugs to avoid elderflower or to use it with caution. Those who are diabetic and may already be using prescription antidiabetic drugs should not use this medicine without consulting their healthcare provider.

4.5. Interaction with other medicines and other forms of interaction

Recommendations

The concomitant use of this medicine with another medicine that is an antidiabetic drug is not recommended because of the elderflower within this medicine. This may potentiate, intensify, and/or prolong antidiabetic drug activity. It is recommended that those who are already using prescription antidiabetic drugs observe the contraindication of concomitant use and consult their healthcare provider before using this medicine.

Although this medicine is indicated for self-administration, and no other forms of interaction have been reported, it is still recommended that a healthcare provider be consulted to avoid patients making dose adjustments to an existing treatment regimen, where the risks may outweigh the benefits. We recommend caution for those with diabetes.

4.6. Fertility, pregnancy and lactation

Although it is unlikely to affect fertility, there is no fertility data available. Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. No adverse effects to fertility, pregnancy, and lactation have yet been reported.

4.7. Effects on the ability to drive and use machines

Although it is unlikely to affect the ability to drive and use machines, this medicine does have antihypertensive properties. No studies on the effect on the ability to drive and use machines have been performed. No adverse effects to the ability to drive or use machines have yet been reported.

4.8. Undesirable effect

No adverse reaction has been reported.

4.9. Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Mechanism of action

The applicable parts of cowslip are the flower and root. The applicable parts of sorrel are the above ground parts. The applicable part of elderflower is the flower. The applicable parts of verbena are the above ground parts. The applicable parts of gentian are the root and bark. The combination of ingredients contains triterpene saponins, flavonol glycosides, methyoxyflavones, and other flavonoids, tannins, consisting of a mixture of proanthocyanidins, including procyanidins and propelargonidins, lectins, lipophilic triterpenoid and sterol compounds such as lupeol and beta-sitosterol, phenolic acids, verbascoside (acetoside), verbenalin, hastatosid, ursolic acid, oleanolic acid, citral, and other terpenoids and iridoids, triterpenoids, xanthones, and other constituents such as lutein.

Pharmacodynamic effects

Due to the triterpene saponins constituents, this medicine may provide therapeutic benefit as an expectorant, associated with its triterpene saponins constituents. In vitro research shows that sorrel extract has activity against the influenza A virus. This is because sorrel extract directly interacts with influenza A particles, blocking viral adsorption, and interfering with penetration at higher concentrations. The procyanidin B2-di-gallate is the main constituent of sorrel responsible for this antiviral effect. The sorrel extract also directly interferes with cell surface receptor binding of the viral hemagglutinin. Regarding elderflower, it appears to have insulin-like activity, enhancing glucose uptake, glucose oxidation, and glycogen synthesis. Additionally, the phenolic compounds present in elderflower have antioxidant activity. Verbena is traditionally used as an anti-inflammatory agent. Traditionally, gentian is used for its analgesic effects, and anti-inflammatory effects can also be attributed to its antioxidant effects. Gentian root has been used historically as an antihypertensive. Gentian root extracts seem to have vasorelaxant properties. Further preliminary research suggests that gentian root extract and its constituent isovitexin can decrease cholesterol in the blood, decrease medial aortic thickness, and decrease smooth muscle proliferation. This suggests that gentian may help prevent atherosclerosis. Moreover, preliminary research also suggests that gentian root exhibits sedative effects. The xanthone gentiacaulein seems to also provide antidepressant activity, possibly through inhibition of monoamine oxidase. These constituents contain properties of benefit as a cough syrup and of benefit to the immune system for symptomatic relief of rhinosinusitis, sinusitis, as well as cold-related and flu-related symptoms.

This evidence is also better understood based on the pharmacokinetic properties of each of the active ingredients as opposed to only an abstract understanding of the pharmacokinetic properties of the Combination Product as a whole (see section 5.2 ‘Pharmacokinetic properties’).

Clinical safety and efficacy

Administered or used according to the recommended maximum and/or total daily dose is likely safe in adults and children, as the substances are generally well-tolerated. However, insufficient data is available to support safety during pregnancy and lactation. Effectiveness studies on the active substances show plausible therapeutic benefits for patients with sinusitis, rhinosinusitis, colds, and flu symptoms, cold-related and flu-related anxiety, and cold-related and flu-related respiratory tract pain and discomfort. However, these active substances are not used to diagnose, treat, cure, or prevent any disease.

It may be unsafe for those with diabetes or those relying on antidiabetic drugs. This is also understood based on the contraindications (see section 4.3 ‘Contraindications’).

5.2. Pharmacokinetic properties

There is limited data available on the exact pharmacokinetic properties of Sinulex® Forte Syrup.

5.3. Preclinical safety data

Non-clinical data obtained on the use of the active substances reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction and development. The long-standing and traditional use of the active substances for which studies reveal plausible therapeutic benefits also provides real-world evidence and data. The use of Sinulex® Forte Syrup is in accordance with low-risk guidelines.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Inactive substances per 7 mL of syrup:

- Sorbitol
- Hydrogen dioxide
- Glycerin
- Tutti frutti Flavour
- Carmellose sodium
- Citric acid
- Sodium benzoate
- Potassium sorbate
- Alcohol

6.2. Incompatibilities

Not applicable; liquid, syrup, oral pharmaceutical forms. No incompatibilities have yet been observed. However, it is recommended to not use or administer simultaneously with other medicines or supplements by allowing some time for digestion of this medicine, or of other orally taken or administered medicines and supplements before use, to avoid any unknown incompatibilities.

6.3. Shelf life

Sinulex® Forte Syrup has an estimated shelf life of 23 months.

6.4. Special precautions for storage

Protect from direct sunlight or moisture. Do not refrigerate or freeze this product. Store in a cool, dry place at temperatures of 59-77° F, equivalent to 15-25° C, and with ambient humidity between 35% and 65%.

Contents must remain sealed before use, shrink-wrapping, or packing into boxes for transport and storage. For express delivery in smaller batches, the use of specialized containment bins may be used for repacking individual sealed units.

6.5. Nature and contents of the container

Sinulex® Forte Syrup comes in cap-sealed bottles of 100 mL syrup per bottle. The active substances provide a total of 858 mg per 7 mL of syrup. Inactive substance per 7 mL of syrup are provided also (see section 6.1 ‘List of excipients’).

Sinulex® Forte Syrup has a 7 mL of syrup dosage form with a specific appearance: Liquid, syrup, opaque maple color, pourable viscosity, markings not applicable. The carton acts as the secondary packaging for storage, also showing the proper labeling.

6.6. Special precautions for disposal and other handling

Return all unused medicine to your pharmacist. Do not dispose of remaining medicines in drains or sewerage systems. Please recycle the empty containers. Expired stock of Sinulex® Forte Syrup is to be quarantined in a special holding facility. Upon quarantine, they must be scheduled for destruction and may accumulate to certain holding levels depending on quarantine capacity.

The expired medicines should be destroyed by those duly authorized to carry out or conduct the destruction.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Tara Pharmaceuticals (Pty) Ltd
36 Sovereign Drive, Route 21 Corporate Park, Irene, Gauteng, 0062, South Africa

8. REGISTRATION NUMBER(S)

Item to be completed by SAHPRA or by the Holder of Certificate of Registration once the authorization has been granted.

9. DATE OF FIRST AUTHORIZATION / RENEWAL OF AUTHORIZATION

Not yet assigned.

10. DATE OF REVISION OF TEXT

Not yet assigned.