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

PROFESSIONAL INFORMATION: CONTENT UNDER EACH HEADING

- This product is 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 Capsules

Strength

391.81 mg per capsule

Pharmaceutical form

Capsule, hard gelatin, solid oral

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

L-ascorbic acid (Vitamin C)	300 mg
Amoracia rusticana G. Gaertn. (Horseradish) [Root, 4:1 extract]	50 mg
Zinc sulfate heptahydrate providing zinc (elemental) 4.9 mg	21.8 mg
Pelargonium sidoides DC. (Pelargonium) [Root, 5:1 extract]	20 mg
Cholecalciferol (Vitamin D3)	300 IU 7.5 µg

Excipients:

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

Sugar-free:

- Does not contain sweeteners.

3. PHARMACEUTICAL FORM

Capsule, hard gelatin, white and yellow, 21.6mm lock length, no markings.

4. CLINICAL PARTICULAR

4.1. Therapeutic indications

- To support the immune system to deal with allergens, colds, flu, and sinusitis for better overall health.
- Due to the active substances, Sinulex® Forte Capsules are indicated for therapeutic use only from the age of 6 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 and can be used to maintain healthy levels of Vitamin C, Vitamin D3, and Zinc.
- It is a health supplement that contains important immunomodulator and immunostimulant properties and can be used to support the respiratory tract, supporting the paranasal sinuses.
- Sinulex® Forte Capsules are 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.
- When using Sinulex® Forte Capsules for maintenance therapy, it is specifically indicated for the purposes of maintaining healthy levels of its key ingredients and is not indicated for alternative maintenance therapy.
- It is not indicated as a cure-all or monotherapy for serious conditions because Sinulex® Forte Capsules are 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, 391.81 mg per capsule.

The potency of this medicine is expressed in capsule 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 years, adults, and the elderly

1 capsule, 3 times daily. This is the maximum recommended daily and/or total dose.

Children below the age of 6 years

1 capsule, 2 times daily. 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. Those using prescription immunosuppressants should avoid using this medicine as it has immunostimulant effects. 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 Capsules is not established as safe for use in persons younger than 6 years of age. Adequate care must be taken to keep this medicine out of the reach of children. Take special precautions for those using immunosuppressants. In the absence of sufficient data, the use of this medicine by those using immunosuppressants is not recommended.
The maximum recommended daily and/or total dose should not be exceeded. Sinulex® Forte Capsules contains coumarin that has anticoagulant effects. Although it is unlikely to occur, it can have moderate effects. Because of coumarin, those who are using prescription blood thinners should be cautious or should avoid using this medicine without consulting their healthcare provider. Do not use this medicine for at least two weeks before surgery or a dental procedure.

4.5. Interaction with other medicines and other forms of interaction

Recommendations

The concomitant use of this medicine with another medicine that is an immunosuppressant is not recommended because of the immunostimulant effects of this medicine. Using this medicine with prescription anticoagulants may potentiate, intensify, and/or prolong blood-thinning activity. It is recommended that those who are already using prescription immunosuppressants and anticoagulants 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 autoimmune diseases who may be relying on immunosuppressant medications.

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 on 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, no studies on the effect on the ability to drive and use machines have been performed. No adverse effects on 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

Vitamin C is water-soluble vitamin that is commonly used due to its physiological functions. The applicable part of horseradish is the root. Zinc is a biologically essential trace element and is the second most abundant trace element in the body. The applicable part of *Pelargonium sidoides* DC. is the root. Active constituents include coumarins, hydrolysable tannins such as umckalin, catechin, gallocatechin, gallic acid ellagitannins, other polyphenols, and proanthocyanidins. Cholecalciferol is synthesized in the skin via 7-dehydrocholesterol, a cholesterol precursor.

Pharmacodynamic effects

The pharmacodynamic effects of the active substances contained in the Combination Product of Sinulex® Forte Capsules exhibit anti-allergic effects that are of interest regarding Vitamin C for allergies such as allergic rhinitis. There are antioxidant effects of Vitamin C which are congruent with its free-radical scavenging effects. The antihypertensive effects appear plausible as well as the anti-inflammatory effects of Vitamin C. Additionally, anti-sepsis effects are of interest due to Vitamin C.
Moreover, antibacterial effects are attributed to horseradish which has antimicrobial efficacy against Gram-negative and Gram-positive bacteria. Other cardiovascular effects are due to evidence that horseradish can stimulate local blood flow.
Through the anti-inflammatory effects of zinc theoretically associated with low levels of zinc during inflammation, supplementation may exhibit additional benefits. The antiviral effects are not clear, but it appears that zinc can inhibit rhinovirus replication in vitro, but it is unclear whether this happens in vivo. Because zinc plays an important role for neutrophils, natural killer cells, and T-lymphocyte function, it has additional immunomodulating effects that appear beneficial to overall health. The importance of zinc in supporting healthy vision is a key ocular effect.
By containing coumarin constituents, the *Pelargonium sidoides* DC. root extract possesses moderate anticoagulant effects but with unlikely interaction occurrences with other drugs based on information available at this time. The extract also has antimicrobial effects, also against certain multi-drug resistant bacteria. More antiviral effects for this root extract are ascertained through in vitro studies on the herpes simplex virus. Furthermore, immunomodulatory effects appear to benefit those with bronchitis and other respiratory disorders, and are thought to be associated with the antimicrobial and immunostimulatory effects of the root extract. By improving symptoms of respiratory disorders, the respiratory effects of this root extract also present potential therapeutic benefits through mucolytic effects, which could improve symptoms in respiratory disorders. It improves cilia function in vitro.
Vitamin D possesses further respiratory effects that may be beneficial and there is interest in using vitamin D for improving respiratory disorders such as bronchitis, chronic obstructive pulmonary disorder (COPD), and asthma. Epidemiological evidence suggests Vitamin D levels in serum are associated with pulmonary function and might also be involved in the remodeling of lung tissues.

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 the common cold, respiratory tract infections (RTIs), acute bronchitis, upper RTIs, rhinosinusitis, and chronic obstructive pulmonary disease (COPD). However, these active substances are not used to diagnose, treat, cure, or prevent any disease.

It may be unsafe for those relying on immunosuppressants. 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 Capsules.

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 Capsules is in accordance with low-risk guidelines.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Inactive substances per capsule:

- Maize starch
- Microcrystalline cellulose
- Magnesium stearate
- Silicone dioxide

6.2. Incompatibilities

Not applicable; solid oral pharmaceutical forms.

6.3. Shelf life

Sinulex® Forte Capsules 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 individually sealed units.

6.5. Nature and contents of the container

Sinulex® Forte Capsules may come in blister packs of 10 capsules or zip-lock sachets of 3 capsules each, as the primary packaging. The active substances provide a total of 391.81 mg per capsule. Inactive substances per capsule are provided also (see section 6.1 ‘List of excipients’).

Sinulex® Forte Capsules has a capsule dosage form with a specific appearance: Capsule, hard gelatin, white and yellow, 21.6mm lock length, and no markings. 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. The expired stock of Sinulex® Forte Capsules 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.