



**SCHEDULING STATUS**

Combination complimentary medicine: D.10.1 (Multi-Vitamin and Herbal/Plant Extracts)

**PROPRIETARY NAME AND DOSAGE FORM**

Sinulex Forte effervescent tablets 12's

**COMPOSITION**

**THE ACTIVE SUBSTANCES ARE:**

L-Ascorbic Acid (Vitamin C)	300 mg
Echinacea Purpurea extract (plant extract 125 mg of 4:1 extract)	500 mg
Horseradish Extract (root extract 50 mg of 4:1 extract)	200 mg
Zinc Gluconate (equivalent to 2 mg elemental Zinc)	16,7 mg
Cholecalciferol (8,333 µg Vitamin D3)	333 IU

**THE OTHER INGREDIENTS ARE:**

Sugar: Galen IQ and Isomalt (sugar alcohol)	1420 mg
Sweetener: Sucralose / Acesulfame K	10 mg

**PHARMACOLOGICAL ACTION:**

Echinacea Purpurea extract is a clinically and pharmacologically well documented modern plant-based medicine for upper respiratory tract infections. Unlike other sinusitis, cough, cold and flu remedies, this unique extract contained in the preparation Sinulex Forte effervescent not only relieves symptoms, but also shortens the duration of the illness itself. It has a unique pharmacological profile which is ideal for the treatment of respiratory tract infections: It activates anti-viral defences, fights bacteria. Horseradish has shown to have a strong mucolytic action. Vitamin C supports a healthy immune system. Cholecalciferol (Vitamin D3) supports a strong immune system. Zinc Gluconate is the best form of Zinc for preventing and treating colds. Clinical studies showed that zinc significantly shortens the duration of symptoms during rhinovirus infections.

**INDICATION:**

Sinulex's comprehensive formula supports the body's ability to naturally deal with allergens, cold, flu and sinusitis for healthier airways and a clear head.

**CONTRA-INDICATIONS:**

Known hypersensitivity to any of the ingredients mentioned under "COMPOSITION" See "Pregnancy and Lactation"

**WARNINGS AND SPECIAL PRECAUTIONS:**

Do not take this medication if you have an autoimmune disorder such as rheumatoid arthritis, lupus or psoriasis. Allergic reactions to any of the ingredients mentioned.

**INTERACTIONS:**

No interactions studies have been performed. Take Sinulex under the supervision of your healthcare practitioner while using blood thinning medication (e.g. Warfarin).

**PREGNANCY AND LACTATION:**

Safety during pregnancy and lactation has not been established.

**DOSAGE AND DIRECTIONS FOR USE:**

**Acute Dosage:**

Adults and children above 12: Dissolve 1 tablet in 200 ml room temperature water three times a day. Children 6 – 12 years: Dissolve ½ 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 12 years: Dissolve 1 tablet in 200 ml room temperature water once daily. Children 6 -12 years: Dissolve ½ a tablet in 200 ml room temperature water once daily Or as prescribed by your healthcare professional. Do not exceed the recommended daily dosage.

**SIDE EFFECTS:**

Known hypersensitivity (allergies) to any of the mentioned ingredients.

**WARNING:**

Do not take this medication if you have an autoimmune disorder such as rheumatoid arthritis, lupus or psoriasis.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**

Treatment is supportive and symptomatic.

**IDENTIFICATION**

12's Sinulex Forte effervescent tablets are a yellow colour effervescent tablets, packed in an effervescent tube with a cap in a box.

**PRESENTATION**

Sinulex Forte effervescent tablets are a yellow colour tablets, packed in an effervescent tube with a cap in a box.

**STORAGE INSTRUCTIONS**

Keep in a dry, cool place below 25 °C. Protect from light.

**REGISTRATION NUMBER**

Will be allocated on registration

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION**

Tara Pharmaceuticals (Pty) Ltd  
Unit 9, Fish Eagle Park  
Old Paardevlei Road  
Somerset West  
7130  
South Africa

**DATE OF PUBLICATION OF THIS PACKAGE INSERT**

25 August 2014

**REGISTRATION DATE:**

Will be allocated on registration

**PATIENT INFORMATION LEAFLET**

Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to use Sinulex Forte effervescent tablets carefully to obtain the best results.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must consult a doctor if your symptoms worsen or do not improve.
- If you notice any side effects, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Sinulex Forte effervescent tablets are and what they are used for
2. Before you take Sinulex Forte effervescent tablets
3. How to take Sinulex Forte effervescent tablets
4. Possible side effects
5. Storing Sinulex Forte effervescent tablets
6. Further information

**1. What Sinulex Forte effervescent tablets are and what they are used for:**

Sinulex Forte effervescent tablets contain Echinacea Purpurea extract, Horseradish extract and Ascorbic acid to help relieve colds, flu, sinusitis, and seasonal allergy symptoms. Cholecalciferol (Vitamin D3) supports a strong immune system. Zinc Gluconate is the best form of Zinc for preventing and treating colds. Clinical studies showed that zinc significantly shortens the duration of symptoms during rhinovirus infections.

The active ingredients in Sinulex Forte effervescent tablets have strong anti-inflammatory, antiviral, antibacterial and antifungal properties that may help to reduce inflammation and fight infections, bacteria and viruses that can cause respiratory infections and congestion.

**2. Before you take Sinulex Forte effervescent tablets:**

**Do not take this medicine if:**

- you are allergic (hypersensitive) to any of the ingredients in Sinulex Forte effervescent tablets.
- it is for a child younger than 6 years.

**Taking other medicines:**

Sinulex Forte effervescent tablets are not known to interact with other medicines.

**Pregnancy and Breastfeeding:**

Sinulex Forte effervescent tablets safety has not been established during pregnancy or breastfeeding.

**Warning:**

Do not take this medication if you have an autoimmune disorder such as rheumatoid arthritis, lupus or psoriasis.

**3. How to take Sinulex Forte effervescent tablets:**

Sinulex Forte effervescent tablets can be used by adults, the elderly and by children over 6 years old.

**Acute Dosage:**

Adults and children above 12: Dissolve 1 tablet in 200 ml room temperature water three times a day. Children 6 – 12 years:

Dissolve ½ 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 12 years: Dissolve 1 tablet in 200 ml room temperature water once daily.

Children 6 -12 years:

Dissolve ½ a tablet in 200 ml room temperature water once daily Or as prescribed by your healthcare professional.

Do not exceed the recommended daily dosage.

If the condition does not improve or becomes worse, consult your doctor, nurse or pharmacist.

**If you miss a dose:**

Take a tablet as soon as you remember then adjust the time for the next dose. Do not take two tablets at the same time to make up for the missed dose.

**If you take too many:**

Do not take more than 3 tablets in a 24-hour period. Taking too much can cause an upset stomach. If you feel discomfort, tell your doctor or your pharmacist.

**4. Possible side effects:**

No side effects have been reported for Sinulex Forte effervescent Tablets. If you feel any side effects or unwell after taking Sinulex Forte effervescent Tablets, stop using it immediately and tell your doctor or pharmacist straightaway.

**5. Storing Sinulex Forte effervescent Tablets:**

Store at or 25 °C in a dry place to protect it against moisture. Keep out of the reach and sight of children. Do not use Sinulex Forte effervescent Tablets after the date (month and year) printed after "USE BY" on the pack. If the expiry date has passed.

**6. Further information:**

Sinulex Forte effervescent tablets are a yellow colour tablets, packed in an effervescent tube with a cap in a box.

**Active substances:**

Each effervescent tablet contains.	
L-Ascorbic Acid (Vitamin C)	300 mg
Echinacea Purpurea extract (plant extract 125 mg of 4:1 extract)	500 mg
Horseradish Extract (root extract 50 mg of 4:1 extract)	200 mg
Zinc Gluconate (equivalent to 2 mg elemental Zinc)	16,7 mg
Cholecalciferol (8,333 µg Vitamin D3)	333 IU

**Other ingredients:**

Sugar: Galen IQ and Isomalt (sugar alcohol)	1420 mg
Sweetener: Sucralose / Acesulfame K	10 mg

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7130  
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This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

