

Sinarest-CCF Tablets

COMPOSITION

Each film coated tablet contains:

Paracetamol IP	500 mg
Chorpheniramine maleate	2 mg
Ambroxol hydrochloride	30 mg
Guaiphenesin	100 mg
Phenylephrine hydrochloride	10 mg

PHARMACOLOGY

Sinarest CCF contains a clinically proven analgesic-antipyretic Paracetamol with antihistamine Chlorpheniramine maleate, mucokinetic Ambroxol, expectorant Guaiphenesin and decongestant Phenylephrine hydrochloride.

Paracetamol is equal to aspirin in analgesic and antipyretic effectiveness and it is unlikely to produce many of the side effects associated with aspirin and aspirin-containing products. Paracetamol produces analgesia by elevation of the pain threshold and antipyretic effect through action on the hypothalamic heat-regulating centre.

Chlorpheniramine maleate is a first generation antihistamine which provides prompt relief of itchy-watery eyes, runny nose, sneezing, itching of the nose or throat due to respiratory allergies. The effectiveness of first-generation antihistamines in blocking sneezing in colds may be due primarily to neuropharmacological manipulation of histaminic and muscarinic receptors in the medulla.

Ambroxol is the metabolite of Bromhexine and a mucolytic agent. Ambroxol acts to reduce the viscosity of tenacious mucous secretions by fragmenting long mucopolysaccharide chains. This results in liquefaction of viscid, mucoid respiratory secretions, which aids expectoration. A wide range of pharmacological anti-inflammatory properties of ambroxol have been described *in vitro* and *in vivo*, including inhibition or scavenging of oxidative and nitrosative stress, increase of local defense molecules involved in respiratory virus replication, reduction of proinflammatory cytokines and arachidonic acid metabolites, inflammatory cell chemotaxis, and lipid peroxidation of tissues.

Guaiphenesin is an expectorant that increases respiratory tract fluid secretions and helps loosen phlegm and bronchial secretions. By reducing the viscosity of secretions, guaiphenesin increases the efficiency of the mucociliary mechanism in removing accumulated secretions from the upper and lower airway. Guaifenesin inhibits cough reflex sensitivity in subjects with URI, whose cough receptors are transiently hypersensitive. Possible mechanisms include a central antitussive effect or a peripheral effect by increased sputum volume serving as a barrier shielding cough receptors within the respiratory epithelium from the tussive stimulus.

Phenylephrine is a sympathomimetic vasoconstrictor that has been used as a nasal decongestant for many years. Phenylephrine constricts the blood vessels in the nasal mucous membranes and allows the air passages to open up. It is a relatively selective alpha-adrenoceptor agonist. The majority of the sympathomimetic action is due to direct stimulation of the adrenoceptors. At

therapeutic doses, it does not cause significant stimulation of the central nervous system.

The pharmacokinetics of this combination of **Sinarest-CCF** are well matched and synergistic. All the drugs are well absorbed orally.

INDICATIONS

Sinarest-CCF Tablets are indicated in the treatment of upper respiratory tract infections associated with cough, cold, fever and bodyache.

DOSAGE & ADMINISTRATION

Adults: The usual recommended dose is 1 tablet tid or qid.

CONTRAINDICATIONS

The use of **Sinarest-CCF Tablet** is contraindicated in patients with:

- Hypersensitivity to any of the ingredients of the formulation.
- Severe hypertension.

PRECAUTIONS

- In case a hypersensitivity reaction occurs which is rare, **Sinarest-CCF Tablet** should be discontinued.
- **Sinarest-CCF Tablet** contains Paracetamol and therefore should not be used in conjunction with other Paracetamol containing products.
- **Sinarest-CCF Tablet** should be used with caution in patients with renal or hepatic dysfunction, diabetes mellitus, hyperthyroidism, cardiovascular problems, epilepsy and closed angle glaucoma.
- It is advisable not to drive or operate machinery when on treatment with **Sinarest-CCF Tablet**.
- Concurrent administration of CNS depressants may have additive effect leading to sedation/somnolence.

DRUG INTERACTIONS

Clinically significant drug interactions may occur on concomitant administration of **Sinarest-CCF Tablet** with monoamine oxidase inhibitors, tricyclic antidepressants, beta-adrenergic agents, methyl dopa, reserpine and veratrum alkaloids.

ADVERSE EFFECTS

Sinarest-CCF Tablet is generally well tolerated and adverse events are rare.

Hypersensitive individuals may display ephedrine-like reactions such as tachycardia, palpitations, headache, dizziness and nausea. Use of sympathomimetics has been associated with fear, anxiety, restlessness, tremor, weakness, dysuria, insomnia, hallucinations and convulsions. Chlorpheniramine may cause sedation. Ambroxol may cause abdominal discomfort and hypersensitivity reactions. Guaiphenesin may cause gastrointestinal discomfort, nausea and vomiting.

PREGNANCY & LACTATION

Pregnancy

There are no adequate and well-controlled studies in pregnant women. **Sinarest-CCF Tablet** should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation

The oral bioavailability of phenylephrine is only about 40%, so the drug is unlikely to reach the infant in large amounts. However, intravenous or oral administration of phenylephrine might decrease milk production. Because no information is available on the use of oral phenylephrine during breastfeeding, **Sinarest-CCF Tablet** should be avoided especially while nursing a newborn or preterm infant.

PRESENTATION

SINAREST-CCF Tablet is available in a blister of 10 tablets.