# SINAREST FXP TABLET

## **COMPOSITION**

Each SINAREST FxP Tablet contains:

Paracetamol IP 500 mg

Phenylephrine hydrochloride IP 10 mg

Fexofenadine 60 mg

#### **DESCRIPTION**

SINAREST FxP Tablet contains a clinically proven analgesic-antipyretic Paracetamol with decongestant Phenylephrine and an antihistamine Fexofenadine. Paracetamol produces analgesia by elevation of the pain threshold and antipyretic effect through action on the hypothalamic heat- regulating center.

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.

Sympathomimetic decongestants reduce the nasal congestion due to increased nasal blood flow associated with colds and influenza. Phenylephrine is sympathomimetic vasoconstrictor that has been used as a decongestant. It is a relatively selective alpha-adrenoceptor agonist. The majority of the sympathomimetic action is due to direct stimulation of the adrenoceptors and relatively little is due to an indirect effect via release of noradrenaline. Its pressor action is weaker than that of noradrenaline but of longer duration. At therapeutic doses, it does not cause significant stimulation of the central nervous system.

Fexofenadine in SINAREST FxP Tablet provides prompt relief of itchy- watery eyes, runny nose, sneezing, itching of the nose or throat due to respiratory allergies. Fexofenadine is an antihistamine with selective peripheral H1-receptor antagonist activity. No sedative or other central nervous system effects were usually observed.

The pharmacokinetics of this combination of SINAREST FxP Tablet is well matched and synergistic. All the drugs are well absorbed orally.

#### **INDICATIONS**

SINAREST FxP Tablet is indicated for:

- Rhinopharyngitis
- Rhinitis with Deviated Nasal Symptoms
- Tonsillitis

#### **DOSAGE & ADMINISTRATION**

Adults: The usual recommended dose is 1 tablet BID.

## CONTRAINDICATIONS

The use of SINAREST FxP 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 FxP Tablet should be discontinued.

SINAREST FxP Tablet contains Paracetamol and therefore should not be used in conjunction with other Paracetamol containing products.

SINAREST FxP 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 Tablet.

## **DRUG INTERACTIONS**

Clinically significant drug interactions may occur on concomitant administration of SINAREST FxP Tablet with monoamine oxidase inhibitors, tricyclic antidepressants, beta-adrenergic agents, methyldopa, reserpine and veratrum alkaloids.

## **ADVERSE REACTIONS**

SINAREST FxP 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 sympathomimetic has been associated with fear, anxiety, restlessness, tremor, weakness, dysuria, insomnia, hallucinations and convulsions. Fexofenadine may cause mild sedation.

# **PRESENTATION**

SINAREST FxP Tablet is available in a blister of 10 tablets.