# Sinarest® FX Tablets

## 1. Composition

Fexofenadine 120mg

## 2. Dosage form and strength

Sinarest FX Tablets are in pack of 10 tablets.

## 3. Clinical particulars

### 3.1 Therapeutic indication

Sinarest FX Tablets are used in management of seasonal allergic rhinitis to get relief from:

- Rhinorrhea
- Sneezing
- Itchy eyes

### 3.2 Posology and method of administration

The usual recommended oral dose for adult is one tablet once a day.

### 3.3 Contraindication

Sinarest FX Tablets are contraindicated in patients allergic to fexofenadine or any of the other ingredients of this product.

### 3.4 Special warnings and precautions for use

- Co-administration with grapefruit, apple, or orange juice reduces bioavailability of fexofenadine by inhibiting P-gp; separate administration by at least 4 hr
- Caution is advised if patient has diabetes, phenylketonuria (PKU), or any other condition that requires limit/avoid these substances in diet.

### 3.5 Drug interactions

Sinarest FX Tablets interactions with:

- Erythromycin
- Ketoconazole
- Antacids containing aluminium or magnesium

### 3.6 Use in special population

- Pediatric: Sinarest FX Tablets are not suitable for children under 12 years of age.
- Geriatric: No adaptation of the dose is necessary in elderly patients, provided their renal function is normal.
- Liver impairment: Use with caution.
- Renal failure: Use with caution.
- Pregnancy and lactation: Pregnancy category: C: Use with caution if benefits outweigh risks. Animal studies show risk and human studies not available or neither animal nor human studies done.
  Excretion in milk unknown; use with caution

### 3.7 Effects on ability to drive and use machine

Sinarest FX Tablets is unlikely to affect ability to drive or operate machinery. However, patient should check that these tablets do not make them feel sleepy or dizzy before driving or operating machinery.

### 3.8 Undesirable effects

Common side effects are:

- nausea,
- diarrhoea,
- upset stomach,
- muscle or back discomfort or pain,
- sleepiness,
- drowsiness,
- tiredness,
- headache, and
- Menstrual cramps.

### 3.9 Overdose

There is limited experience of overdose with Sinarest FX Tablets. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

## 4. Pharmacological properties

### 4.1 Mechanism of action

Like other H1-blockers, Fexofenadine competes with free histamine for binding at H1-receptors in the GI tract, large blood vessels, and bronchial smooth muscle. This block the action of endogenous histamine, which subsequently leads to temporary relief of the negative symptoms (eg. nasal congestion, watery eyes) brought on by histamine. Fexofenadine exhibits no anticholinergic, antidopaminergic, alpha1-adrenergic or beta-adrenergic-receptor blocking effects.

### 4.2 Pharmacodynamic properties

Fexofenadine is a second-generation, long lasting H1-receptor antagonist (antihistamine) which has a selective and peripheral H1-antagonist action. Histamine is a chemical that causes many of the signs that are part of allergic reactions, such as the swelling of tissues. Histamine is released from histamine-storing cells (mast cells) and attaches to other cells that have receptors for histamine. The attachment of the histamine to the receptors causes the cell to be "activated," releasing other chemicals which produce the effects that we associate with allergy. Fexofenadine blocks one type of receptor for histamine (the H1 receptor) and thus prevents activation of cells by histamine. Unlike most other antihistamines, Fexofenadine does not enter the brain from the blood and, therefore, does not cause drowsiness. Fexofenadine lacks the cardiotoxic potential of terfenadine, since it does not block the potassium channel involved in repolarization of cardiac cells.

### 4.3 Pharmacokinetic properties

Fexofenadine is rapidly absorbed after oral doses with peak plasma concentrations being reached in 2 to 3 hours. It is about 60 to 70% bound to plasma proteins. About 5% of the total dose is metabolised, mostly by the intestinal mucosa, with only 0.5 to 1.5% of the dose undergoing hepatic biotransformation by the cytochrome P450 system. Elimination half-life of about 14 hours has been reported although this may be prolonged in patients with renal impairment. Excretion is mainly in the faeces with only 10% being present in the urine. Fexofenadine does not appear to cross the blood brain barrier. Fexofenadine is a metabolite of terfenadine and as such has been detected in breast milk after the administration of terfenadine.

## 5. Nonclinical properties

### 5.1 Animal Toxicology or Pharmacology

Not required.

## 6. Description

Already mentioned and covered in the above points.

## 7. Pharmaceutical particulars

### 7.1 Incompatibilities

There are no known incompatibilities.

### 7.2 Shelf-life

24 months.

### 7.3 Storage and handling instructions

Store in cool and dry place.