

# Fondy™ 120

Fexofenadine Hydrochloride USP 120 mg

## COMPOSITION

**Fondy™ 120 Tablet:** Each film coated tablet contains Fexofenadine Hydrochloride USP 120 mg.

## DESCRIPTION

**Fondy™ 120** is a pink, round-concave tablet. Fexofenadine Hydrochloride, the active ingredient of **Fondy™**, is a histamine H1-receptor antagonist with the chemical name (±)-4-[1 hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]-butyl]- $\alpha$ ,  $\alpha$ -dimethyl benzeneacetic acid hydrochloride.

## CLINICAL PHARMACOLOGY

### MECHANISM OF ACTION

Fexofenadine Hydrochloride is an antihistamine with selective peripheral H1-receptor antagonist activity. Both enantiomers of Fexofenadine Hydrochloride displayed approximately equipotent antihistaminic effects. Fexofenadine inhibited histamine release from peritoneal mast cells with no anticholinergic,  $\alpha$ 1-adrenergic or  $\beta$ -adrenergic-receptor blocking effects, sedative or other central nervous system (CNS) effects as it does not cross the blood-brain-barrier (BBB).

### PHARMACOKINETICS

**Absorption:** Fexofenadine Hydrochloride is rapidly absorbed following oral administration with a mean time to maximum plasma concentration occurring at 2.6 hours post-dose and mean plasma concentration of 142-494 ng/mL. Bioavailability of Fexofenadine is approximately 33%.

**Distribution:** Fexofenadine Hydrochloride is 60%-70% bound to plasma proteins, primarily albumin and  $\alpha$ 1-acid glycoprotein.

**Metabolism:** Approximately 5% of total oral dose is metabolized in the liver.

**Elimination:** The mean elimination half-life of Fexofenadine is 14.4 hours, most of the Fexofenadine dose is eliminated via feces (80%) and urine (11%)

### INDICATIONS AND USAGE

**Seasonal Allergic Rhinitis:** **Fondy™** is indicated for the relief of symptoms associated with seasonal and perennial allergic rhinitis in adults and children 6 years of age and older. Symptoms treated effectively including sneezing, rhinorrhea, lacrimation, itchy nose/palate/throat, itchy/watery/red eyes.

**Chronic Idiopathic Urticaria:** **Fondy™** is indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticarial in adults and children 6 years of age and older. It significantly reduces signs and symptoms of chronic idiopathic urticarial, the number of wheals and pruritus.

### DOSAGE AND ADMINISTRATION

#### Seasonal Allergic Rhinitis

**Adults and Children 12 years and older:** The recommended dose of **Fondy™** is 60 mg twice daily or 120-180 mg once daily. A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function.

**Children 6-11 years:** The recommended dose of **Fondy™** is 30 mg twice daily. A dose of 30 mg once daily is recommended as the starting dose in pediatric patients with decreased renal function.

#### Chronic Idiopathic Urticaria

**Adults and Children 12 years and older:** The recommended dose of **Fondy™** is 60 mg twice daily or 120-180 mg once daily. A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function.

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### CONTRAINDICATIONS

**Fondy™** (Fexofenadine Hydrochloride) is contraindicated in patients with known hypersensitivity to any of its ingredients.

### PRECAUTIONS

#### DRUG INTERACTIONS

Since Fexofenadine Hydrochloride does not undergo hepatic biotransformation, it is unlikely to interact with drugs that rely upon hepatic metabolism.

**Antacids:** Fexofenadine should not be taken closely in time with Aluminum and Magnesium containing Antacids. In healthy adult subjects, administration of 120 mg of Fexofenadine Hydrochloride within 15 minutes of an Aluminum and Magnesium containing Antacid decreased Fexofenadine AUC by 41% and Cmax by 43%.

**Erythromycin and Ketoconazole:** Fexofenadine has been shown to exhibit minimal (5%) metabolism. However, co-administration of Fexofenadine Hydrochloride with either Ketoconazole or Erythromycin led to increased plasma concentrations of Fexofenadine in healthy adult subjects.

**Fruit Juices:** Fruit juices such as grapefruit, orange and apple may reduce the bioavailability and exposure of Fexofenadine.

**Use in Special Populations:** Studies in special risk groups (elderly, renally or hepatically impaired patients) indicate that it is not necessary to adjust the dose of Fexofenadine Hydrochloride in these patients.

#### SIDE EFFECTS

In placebo-controlled trials adverse reactions were comparable in Fexofenadine and placebo treated patients.

**Common:** headache

**Uncommon:** fatigue, drowsiness, nausea, tachycardia, palpitations, dry mouth, nose and/or throat, dyspepsia and gastrointestinal disturbances including diarrhea.

**Rare:** taste disturbances, anaphylactic/anaphylactoid reactions, dyspnea, chest tightness, increased hair loss/hair thinning, photosensitivity, dysmenorrhea, menstrual disorders.

#### WARNINGS

##### Effects on ability to drive and use machines

On the basis of pharmacodynamic profile and reported adverse events, it is unlikely that Fexofenadine Hydrochloride tablets will produce an effect on the ability to drive or use machines. In objective tests, Fexofenadine Hydrochloride has been shown to have no significant effects on central nervous system (CNS) function. This means that patients may drive or perform tasks that require concentration.

#### OVER DOSAGE

Most reports of Fexofenadine Hydrochloride overdose contain limited information. However, dizziness, drowsiness and dry mouth have been reported. Single doses up to 800 mg and doses up to 690 mg BID for 1 month or 240 mg QD for 1 year were studied in healthy subjects without the development of clinically significant adverse events as compared to placebo.

#### USE IN PREGNANCY AND LACTATION

There are no adequate and well-controlled studies in pregnant and nursing mother. Therefore, Fexofenadine should be used during pregnancy and lactation only if the potential benefit justifies the potential risk to the fetus and baby.

There are no adequate and well-controlled studies in women during lactation. Because, many drugs are excreted in breast milk, caution should be exercised when Fexofenadine is administered to a nursing woman.

#### STORAGE CONDITION

Store in a cool & dry place, protected from light. Keep out of the reach of children.

#### COMMERCIAL PACK

**Fondy™ 120 Tablet:** Each box contains 30 tablets in 3X10's Alu-PVC blister strips.



Manufactured by:  
**Nuvista Pharma Limited**  
48 Tongi industrial area, Gazipur, Bangladesh  
A subsidiary of Beximco Pharmaceuticals Ltd.

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