

TELFAST

30mg/5ml Oral suspension

120 mg Film coated tablet

180 mg Film coated tablet

Indications:

Oral liquid: Relief of symptom associated with urticarial from 6 months of age. Relief of symptoms associated with seasonal allergic rhinitis from 2 years of age.

120 mg Tablets: Relief of symptoms associated with seasonal allergic rhinitis in adults and children aged 12 years or older.

180 mg Tablets: Relief of symptoms associated with seasonal allergic rhinitis or urticaria in adults and children aged 12 years or older.

Contraindications:

Telfast is contraindicated in patients with a known hypersensitivity to fexofenadine, terfenadine or any of its excipients.

Precautions:

Effects on Fertility

In rat fertility studies, dose-related reductions in implants and increases in post implantation losses were observed at oral doses equal to or greater than 150 mg/kg of terfenadine respectively; these doses produced plasma AUC values of fexofenadine that were equal to or greater than three times the human therapeutic value respectively (based on a 60 mg twice daily fexofenadine HCl dose).

Use in Pregnancy

Reproductive toxicity of fexofenadine in animals was assessed through terfenadine exposure. No evidence of teratogenicity was observed in animal reproduction studies (rat and rabbit) when terfenadine was given at oral doses of up to 300 mg/kg/day throughout organogenesis, which corresponds to levels of systemic fexofenadine exposure 4- and 32-fold higher, respectively, than those anticipated in clinical use.

Decreased pup weight and survival occurred in rats when terfenadine was given at oral doses of 150 mg/kg/day and above throughout pregnancy and lactation. There are no studies in pregnant women exposed to fexofenadine alone or through the administration of terfenadine.

Use in Lactation

Telfast is not recommended for nursing women unless, in the physician's judgment, the potential benefit to the patient outweighs the potential risk to the infant. There are no data on the content of human milk after administering fexofenadine. However, when terfenadine was administered to nursing mothers, fexofenadine was found to cross into human breast milk.

Pediatric use

Safety and effectiveness of Telfast has not been established in children under 2 years of age for allergic rhinitis and under 6 months of age for chronic idiopathic urticaria. Telfast 6- 11 Years tablets is intended for paediatric patients 6 to 11 years of age and Telfast Oral Liquid for children from 6 months.

Carcinogenicity:

The carcinogenic potential and reproductive toxicity of fexofenadine HCl were assessed using terfenadine studies. No evidence of carcinogenicity was observed when mice and rats were given daily oral doses of 50 and 150 mg/kg of terfenadine for 18 and 24 months, respectively; these doses resulted in plasma AUC values of fexofenadine that were two to four times the human therapeutic value (based on a 60 mg twice daily fexofenadine HCl dose). Fexofenadine showed no genotoxic activity in a series of assays for gene mutations and chromosomal damage.

Adverse effects:

Telfast is generally well tolerated, in placebo-controlled trials involving seasonal allergic rhinitis and chronic idiopathic urticaria patients, adverse events were comparable in fexofenadine- and placebo-treated patients. The most common adverse events reported in controlled clinical trials were headache, fatigue, dizziness or drowsiness and nausea. No apparent dose trends were revealed in adverse events.

Events that have been reported during controlled trials involving seasonal allergic rhinitis and chronic idiopathic urticaria patients with incidences less than 1% and similar to placebo. And have been reported merely during postmarketing surveillance include: fatigue, insomnia, nervousness, and sleep disorders or paranoia. In rare cases, rash, urticaria, pruritus and hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis have been reported.

Adverse events reported in placebo-controlled chronic idiopathic urticaria studies were similar to those reported in placebo-controlled seasonal allergic rhinitis studies. In placebo- controlled trials involving paediatric seasonal allergic rhinitis patients (6-11 years of age), adverse events were similar to those observed in trials involving seasonal allergic rhinitis patients 12 years and older.

In controlled clinical trials involving paediatric patients 6 months to 5 years of age, there were no unexpected adverse events in patients treated with fexofenadine hydrochloride. As with adults, the incidence of adverse events with fexofenadine in pediatric patients was similar to placebo.

Dosage and Administration:

Pediatrics:

Allergic rhinitis and seasonal allergic rhinitis: Children aged 2 to 11 years: 30 mg twice daily when required.

Urticaria:

Children aged 6 to 23 years: 15 mg twice daily

Children aged 2 to 11 years: 30 mg twice daily

Adults and children aged over 12 years:

Allergic rhinitis: 60 mg twice daily when required

Seasonal Allergic rhinitis: 120 or 180 mg once daily when required

Urticaria: 180 mg once daily when required

- Always read the full prescribing information.
- Ask the physician or the pharmacist when you start using the medication or when symptoms persist
- Please report any suspected adverse reactions to Egyptian pharmacovigilance center (EPVC) on 15301 and through Sanofi's Pharmacovigilance email chc-pharmacovigillance.eg@sanofi.com

Telfat Ministry of Health. approved leaflet: 29-11-2018

TELFAT DECONGESTANT (fexofenadine HCl 60 mg and pseudoephedrine HCl 120 mg)**Extended-Release Tablets****INDICATIONS AND USAGE**

TELFAT DECONGESTANT Extended-Release Tablets are indicated for the relief of symptoms associated with seasonal allergic Rhinitis in adults and children 12 years of age and older. Symptoms treated effectively include sneezing, rhinorrhea, itchy nose/palate/ and/or throat, itchy/watery/red eyes, and nasal decongestion. TELFAST DECONGESTANT should be administered when both the antihistaminic properties of fexofenadine hydrochloride and the nasal decongestant properties of pseudoephedrine hydrochloride are desired.

CONTRAINDICATIONS

TELFAT DECONGESTANT is contraindicated in patients with known hypersensitivity to any of its ingredients.

WARNINGS

Sympathomimetic amines should be used with caution in patients with hypertension, diabetes

mellitus, ischemic heart disease, increased intraocular pressure, hyperthyroidism, renal impairment, or prostatic hypertrophy. Sympathomimetic amines may produce central nervous system stimulation with convulsions or cardiovascular collapse with accompanying hypotension.

PRECAUTIONS

General

Patients with decreased renal function should be given a lower initial dose (one tablet per day) because they have reduced elimination of fexofenadine and pseudoephedrine.

Effects on Fertility

Reproduction and fertility studies with terfenadine in rats produced no effect on male or female fertility at oral doses up to 300 mg/kg/day. However, reduced implants and post implantation losses were reported at 300 mg/kg.

Use in Pregnancy

Teratogenic Effects: Category C. Terfenadine alone was not teratogenic in rats and rabbits at oral doses up to 300 mg/kg; 300 mg/kg of terfenadine produced fexofenadine AUC values that were approximately 4 and 30 times, respectively, the AUC at the maximum recommended human daily oral dose of TELFAST-D. In mice, no adverse effects and no teratogenic effects during gestation were observed with fexofenadine at dietary doses up to 3730 mg/kg (approximately 15 times the maximum recommended human daily oral dose of TELFAST-D based on comparison of the AUCs).

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

Use in Lactation

It is not known if fexofenadine is excreted in human milk. Because many drugs are excreted in human milk, caution should be used when fexofenadine hydrochloride is administered to a nursing woman.

A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Caution should be exercised when TELFAST-D is administered to nursing women.

Use in Children

Safety and effectiveness of TELFAST-D in children below the age of 12 years have not been established. In addition, the doses of the individual components in TELFAST-D exceed the

recommended individual doses for pediatric patients under 12 years of age. TELFAST-D is not recommended for pediatric patients under 12 years of age.

Carcinogenicity

The carcinogenic potential and reproductive toxicity of fexofenadine hydrochloride were assessed using terfenadine studies with adequate fexofenadine exposure (area-under-the plasma concentration versus time curve [AUC]). No evidence of carcinogenicity was observed when mice and rats were given daily oral doses up to 150 mg/kg of terfenadine for 18 and 24 months, respectively.

Adverse Reactions

In one clinical trial (n=651) in which 215 subjects with seasonal allergic rhinitis received the 60 mg fexofenadine hydrochloride/120 mg pseudoephedrine hydrochloride combination tablet twice daily for up to 2 weeks, adverse events were similar to those reported either in subjects receiving fexofenadine hydrochloride 60 mg alone (n=218 subjects) or in subjects receiving pseudoephedrine hydrochloride 120 mg alone (n=218). A placebo group was not included in this study. The percent of subjects who withdrew prematurely because of adverse events was 3.7% for the fexofenadine hydrochloride/pseudoephedrine hydrochloride combination group, 0.5% for the fexofenadine hydrochloride group, and 4.1% for the pseudoephedrine hydrochloride group. All adverse events that were reported by greater than 1% of subjects who received the recommended daily dose of the fexofenadine hydrochloride/pseudoephedrine hydrochloride combination are listed in the following table. (See Table 1.)

Table 1. Adverse Experiences Reported in One Active-Controlled Seasonal Allergic Rhinitis Clinical Trial at Rates of Greater than 1%.			
Adverse Experience	60 mg Fexofenadine Hydrochloride/ 120 mg Pseudoephedrine Hydrochloride Combination Tablet Twice Daily (n=215)	Fexofenadine Hydrochloride 60 mg Twice Daily (n=218)	Pseudoephedrine Hydrochloride 120 mg Twice Daily (n=218)
Headache	13.0%	11.5%	17.4%
Insomnia	12.6%	3.2%	13.3%
Nausea	7.4%	0.5%	5.0%
Dry Mouth	2.8%	0.5%	5.5%
Dyspepsia	2.8%	0.5%	0.9%
Throat Irritation	2.3%	1.8%	0.5%
Dizziness	1.9%	0.0%	3.2%
Agitation	1.9%	0.0%	1.4%
Back Pain	1.9%	0.5%	0.5%
Palpitation	1.9%	0.0%	0.9%
Nervousness	1.4%	0.5%	1.8%
Anxiety	1.4%	0.0%	1.4%
Upper Respiratory Infection	1.4%	0.9%	0.9%
Abdominal Pain	1.4%	0.5%	0.5%

Dosage & Administration

The recommended dose of TELFAST-D Extended-Release Tablets is ONE tablet twice daily administered on an empty stomach with water for adults and children 12 years of age and older. It is recommended that the administration of TELFAST-D with food should be avoided. A dose of one tablet once daily is recommended as the starting dose in patients with decreased renal function.

- Always read the full prescribing information.
- Ask the physician or the pharmacist when you start using the medication or when symptoms persist
- Please report any suspected adverse reactions to Egyptian pharmacovigilance center (EPVC) on 15301 and through Sanofi's Pharmacovigilance email chc-pharmacovigillance.eg@sanofi.com

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