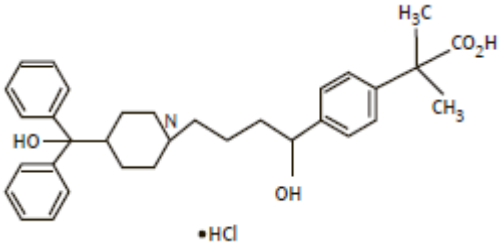
TELFAST®
Fexofenadine HCl 60 mg

Description
Fexofenadine hydrochloride, the active ingredient of TELFAST 60 mg, is a histamine H1-receptor antagonist with the chemical name (+)-4-[1-hydroxy-4-[4-(hydroxydiphenyl-methyl)-1-piperidinyl] - butyl] -a,a-dimethyl benzeneacetic acid hydrochloride, it has the following chemical structure:



The molecular weight is 538.13 and the empirical formula is C32H39NO4.HCl. Fexofenadine hydrochloride is a white to off-white crystalline powder. It is freely soluble in methanol and ethanol, slightly soluble in chloroform and water, and insoluble in hexane. Fexofenadine hydrochloride is a racemate and exists as a zwitterion in aqueous media at physiological pH.

TELFAST 60 mg is formulated as tablet for oral administration. Each film coated tablet contains 60 mg Fexofenadine Hydrochloride and the following excipients: croscarmellose sodium, pregelatinized maize starch, microcrystalline cellulose, magnesium stearate, and purified water. The coated tablet shell is made from hydroxypropyl methylcellulose E-15, hydroxypropyl methylcellulose E-5, povidone, titanium dioxide (E171), colloidal anhydrous silica, macrogol 400, pink iron oxide blend, yellow iron oxide blend and purified water

Product Description
Peach, oblong, double convex, tablet "06" on one side, blank on the other side.

Clinical Pharmacology
Mechanism of action
Fexofenadine, a metabolite of terfenadine, is an antihistamine with selective peripheral H1-receptor antagonist activity. Fexofenadine inhibited antigen-induced bronchospasm in sensitized guinea pigs and histamine release from peritoneal mast cells in rats. In laboratory animals, no anticholinergic or alpha1-adrenergic receptor blocking effects were observed. Moreover, no sedative or other central nervous system effects were observed. Radiolabeled tissue distribution studies in rats indicated that fexofenadine does not cross the blood-brain barrier.

Pharmacokinetics
Fexofenadine Hydrochloride was rapidly absorbed following oral administration of a single dose of two 60 mg tablet to healthy male volunteers with a mean time to maximum plasma concentration occurring at 2.6 hours post dose. After administration of a single 60 mg dose as an oral solution to healthy subjects, the mean plasma concentration was 209 ng/ml. Mean steady-state peak plasma concentrations of 286 ng/mL were observed when healthy volunteers were administered multiple doses of fexofenadine hydrochloride (60 mg oral solution every 12 hours for 10 doses). Fexofenadine pharmacokinetics were linear for oral doses up to 120 mg twice daily. Although the absolute bioavailability of fexofenadine hydrochloride tablet is unknown, the tablet are bioequivalent to an oral solution. The mean elimination half life of fexofenadine was 14.4 hours following administration of 60 mg, twice daily, to steady-state in normal volunteers.

Human mass balance studies documented a recovery of approximately 80% and 11% of the (14C) fexofenadine hydrochloride dose in the feces and urine, respectively. Approximately 5% of the total dose was metabolized. Because the absolute bioavailability of fexofenadine hydrochloride has not been established, it is unknown if the fecal component represents unabsorbed drug or the result of billary excretion.

The pharmacokinetics of fexofenadine hydrochloride in allergic rhinitis patients were similar to those in healthy subjects. Peak fexofenadine plasma concentrations were similar between adolescent (12-16 years of age) and adult patients.
Fexofenadine is 60% to 70% bound to plasma proteins, primarily albumin and a1-acid glycoprotein.

Special Populations
Special population pharmacokinetics (for age and renal and hepatic impairment), obtained after a single dose of 80 mg fexofenadine hydrochloride, were compared to those from normal subjects in a separate study of similar design. While subject weights were relatively uniform between studies, these special population patients were substantially older than the healthy, young volunteers. Thus, an age effect may be confounding the pharmacokinetic differences observed in some of the special populations.

Effect of age. In older subjects (> 65 years old), peak plasma levels of fexofenadine were 99% greater than those observed in normal volunteers (< 65 years old). Mean elimination half-lives were similar to those observed in normal volunteers.

Renally impaired. In patients with mild (creatinine clearance 41-80 ml/min) to severe (creatinine clearance 11-40 ml/min.) renal impairment, peak plasma levels of fexofenadine were 87% and 111% greater, respectively, and mean elimination half-lives were 59% and 72% longer, respectively, than observed in normal volunteers. Peak plasma levels in patients on dialysis (creatinine clearance < 10 ml/min) were 82% greater and half-life was 31% longer than observed in normal volunteers. Based on increases in bioavailability and half-life, a dose of 60 mg once daily is recommended as

the starting dose in patients with decreased renal function. (See DOSAGE AND ADMINISTRATION).

Hepatically impaired. The pharmacokinetics of fexofenadine hydrochloride in patients with hepatic disease did not differ substantially from that observed in healthy subjects.

Effect of Gender. Across several trials, no clinically significant gender related differences were observed in the pharmacokinetics of fexofenadine.

Pharmacodinamics
Wheal and flare. Human histamine skin wheal and flare studies following single and twice daily doses of 20 mg and 40 mg fexofenadine hydrochloride demonstrated that the drug exhibits an antihistamine effect by 1 hour, achieves maximum effect at 2-3 hours, and an effect is still seen at 12 hours. There was no evidence of tolerance to these effects after 28 days of dosing.

Effects on QTc. In dogs, (10 mg/kg/day, orally for 5 days) and rabbits (10 mg/kg, intravenously over one hour) fexofenadine did not prolong QTc at plasma concentrations that were at least 28 and 63 times, respectively, the therapeutic plasma concentrations in man (based on a 60 mg twice daily fexofenadine hydrochloride dose). No effect was observed on calcium channel current, delayed K+ channel current, or action potential duration in guinea pig myocytes, Na+ current in rat neonatal myocytes, or on the delayed rectifier K+ channel cloned from human heart at concentrations up to 1 x 10-5 M of fexofenadine. This concentration was at least 32 times the therapeutic plasma concentration in man (based on a 60 mg twice daily fexofenadine hydrochloride dose).

No statistically significant increase in mean QTc interval compared to placebo was observed in 714 allergic rhinitis patients given fexofenadine hydrochloride tablet in doses of 60 mg to 240 mg twice daily for two weeks or in 40 healthy volunteers given fexofenadine hydrochloride as an oral solution at doses up to 400 mg twice daily for 6 days.

Clinical studies
In three, 2-weeks, multi-centre, randomized, double-blind, placebo-controlled trials in patients 12 - 68 years of age with allergic rhinitis (n=1634), fexofenadine hydrochloride 60 mg twice daily significantly reduced total symptom scores (the sum of the individual scores for sneezing, rhinorrhea, itchy nose/ palate/ throat, itchy/ watery/ red eyes) compared to placebo. Statistically significant reductions in symptom scores were observed following the first 60 mg dose, with the effect maintained throughout the 12-hour interval. In general, there was no additional reduction in total symptom scores with higher doses of fexofenadine up to 240 mg twice daily. Although the number of subjects in some of the subgroups was small, there were no significant differences in the effect of fexofenadine hydrochloride across subgroups of patients defined by gender, age, and race. Onset of action for reduction in total symptom scores, excluding nasal congestion, was observed at 60 minutes compared to placebo following a single 60 mg fexofenadine hydrochloride dose administered to patients with allergic rhinitis who were exposed to ragweed pollen in an environmental exposure unit.

Indications and usage
TELFAST 60 mg is indicated for the relief of symptoms associated with allergic rhinitis in adults and children 12 years of age and older.
Symptoms treated effectively include sneezing, rhinorrhea, itchy nose/ palate/ throat, itchy/ watery/ red eyes.

Contraindications
TELFAST 60 mg is contraindicated in patients with known hypersensitivity to any of its ingredients.

Precautions
As with most new drugs there is only limited data in the elderly and renally or hepatically impaired patients. Fexofenadine hydrochloride should be administered with care in these special groups.

Effects on ability to drive and use machines
On the basis of the pharmaco-dynamic 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, Telfast has been shown to have no significant effects on central nervous system function. This means that patients may drive or perform tasks that require concentration. However, in order to identify sensitive people who have an unusual reaction to drugs, it is advisable to check the individual response before driving performing complicated tasks.

Drug interactions
Fexofenadine does not undergo hepatic biotransformation and therefore will not interact with other drugs through hepatic mechanisms. Co-administration of fexofenadine hydrochloride with erythromycin or ketoconazole has been found to result in a 2-3 times increase in the level of fexofenadine in plasma. The changes were not accompanied by any effects on the QT interval and were not associated with any increase in adverse events compared to the drugs given singly.

Animal studies have shown that the increase in plasma levels of fexofenadine observed after co-administration of erythromycin or ketoconazole, appears to be due to an increase in gastrointestinal absorption and either a decrease in biliary excretion or gastrointestinal secretion, respectively.

No interaction between fexofenadine and omeprazole was observed. However, the administration of an antacid containing and aluminium magnesium hydroxide gels 15 minutes prior to fexofenadine hydrochloride caused a reduction in bioavailability, most likely due to binding in the gastrointestinal tract. It

is advisable to leave 2 hours between administration of fexofenadine hydrochloride and aluminium and magnesium hydroxide containing antacids.

Carcinogenesis, Mutagenesis, Impairment of Fertility.
The carcinogenic potential and reproductive toxicity of fexofenadine hydrochloride were assessed using terfenadine studies with adequate fexofenadine exposure (based on plasma area under the curve [AUC] values). 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 up to four times the human therapeutic value (based on a 60 mg twice-daily fexofenadine hydrochloride dose).

In in-vitro (Bacterial Reserve Mutation, CHO/HGPRT Forward Mutation, and Rat Lymphocyte Chromosomal Aberration assays) and in-vivo (Mouse Bone Marrow Micronucleus assay) tests, fexofenadine hydrochloride revealed no evidence of mutagenicity.

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; these doses produced plasma AUC values of fexofenadine that were equal to or greater than three times the human therapeutic value (based on a 60 mg twice daily fexofenadine hydrochloride dose).

Pregnancy
Teratogenic Effects: Category C. There was no evidence of teratogenicity in rats or rabbits at oral terfenadine doses up to 300 mg/kg; these doses produced fexofenadine plasma AUC values that were up to 4 and 37 times the human therapeutic value (based on a 60-mg twice-daily fexofenadine hydrochloride dose), respectively.

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

Non teratogenic effects: Dose-related decreases in pup weight gain and survival were observed in rats exposed to oral doses equal to and greater than 150 mg/kg of terfenadine; at these doses the plasma AUC values of fexofenadine were equal to or greater than 3 times the human therapeutic values (based on a 60-mg twice daily fexofenadine hydrochloride dose).

Nursing Mothers
Not recommended

Pediatric Use
Safety and effectiveness of TELFAST 60 mg in pediatric patients under the age of 12 years have not been established. Across well-controlled clinical trials in patient with allergic rhinitis, a total of 205 patients between the ages of 12 to 16 years received doses ranging from 20 mg to 240 mg twice daily for up to two weeks. Adverse events were similar in this group compared to patients above the age of 16 years.

Geriatric Use
In placebo-controlled trials, 42 patients, age 60 to 68 years, received doses of 20 mg to 240 mg of fexofenadine twice daily for up to two weeks. Adverse events were similar in this group to patients under age 60 years.

Adverse reactions
In placebo-controlled clinical trials, which included 2461 patients receiving fexofenadine hydrochloride at doses of 20 mg to 240 mg twice daily, adverse events were similar in fexofenadine hydrochloride and placebo-treated patients. The incidence of adverse events, including drowsiness, was not dose related and was similar across subgroups defined by age, gender, and race. The percent of patients who withdrew prematurely because of adverse events was 2.2% with fexofenadine hydrochloride vs 3.3 % with placebo. All adverse events that were reported by greater than 1% of patients who received the recommended daily dose of fexofenadine hydrochloride (60 mg twice-daily), and that were more common with fexofenadine than placebo, are listed in the following table:

Adverse Experiences Reported in Placebo-Controlled Allergic Rhinithis Clinical Trials at Rates of Greater than 1%

Adverse Expericene	Fexofenadine 60 mg Twice daily (n=679)	Placebo Twice daily (n=671)
Viral infection (Cold, flu)	2.5%	1.5%
Nausea	1.6%	1.5%
Dysmenorrhea	1.5%	0.3%
Drowsiness	1.3%	0.9%
Dyspepsia	1.3%	0.9%
Fatigue	1.3%	0.9%

Adverse events occuring in greater than 1% of fexofenadine hydrochloride treated patients (60 mg twice daily), but that were more common in the placebo treated group, include headache and throat irritation. The frequency and magnitude of laboratory abnormalities were similar in fexofenadine hydrochloride and placebo treated patients.

Reporting of suspected adverse reactions
Report immediately if you experience any adverse reaction or undesirable condition during and after using the medicinal product to farmakovigilans@kalventis.com.

Overdosage
Information regarding acute overdosage is limited to experience from clinical trials conducted during the development of TELFAST 60 mg. Single doses of

fexofenadine hydrochloride up to 800 mg (6 normal volunteers at this dose level), and doses up to 690 mg twice daily for one months (3 normal volunteers at this dose level), were administered without the development of clinically significant adverse events.

In the event of overdose, consider standard measures to remove any unabsorbed drug. Symptomatic and supportive treatment is recommended. Hemodialysis did not effectively remove fexofenadine from blood (up to 1.7% removed) following terfenadine administration.

No deaths occured at oral doses of fexofenadine hydrochloride up to 5000 mg/kg in mice (170 times the maximum recommended human daily oral dose based on mg/m²) and up to 5000 mg/kg in rats (330 times the maximum recommended human daily oral dose based on mg/m²).

Additionally, no clinical signs of toxicity or gross pathological findings were observed. In dogs, no evidence of toxicity was observed at oral doses up to 2000 mg/kg (450 times the maximum recommended human daily oral dose based on mg/m²).

Dosage and administration
The recommended dose of TELFAST 60 mg is 60 mg twice daily for adults and children 12 years of age and older. A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function. (See CLINICAL PHARMACOLOGY).

Storage
Store at temperature below 30°C.

Presentation:
Box contains 1 blister x 10 film coated tablets
Reg.No. DTL1121205217A1

Manufactured by:
PT Kalventis Sinergi Farma,
Jakarta, Indonesia

Under license from:
Opella Healthcare International SAS, France

Revision date: 30 April 2025

Telfast®
Fexofenadine HCl 60 mg

Apa itu Telfast® 60 mg?
Telfast® 60 mg mengandung Fexofenadine HCl, antihistamin (anti-alergi) generasi ketiga yang efektif meringankan gejala rinitis alergi seperti bersin, pilek, gatal hidung/langit-langit mulut/ tenggorokan, dan mata merah/berair/gatal.

Sediaan Telfast® 60 mg	Kekuatan	Deskripsi Produk
Tablet salut selaput	60 mg	Tablet berwarna *peach*, berbentuk lonjong dan cembung di kedua sisi, satu sisi terdapat tanda "06" dan sisi lainnya polos.

Zat tambahan: *croscarmellose sodium, pregelatinized maize starch, microcrystalline cellulose, magnesium stearate dan purified water, hydroxypropyl methylcellulose E-15, hydroxypropyl methylcellulose E-5, povidone, titanium dioxide (E 171), colloidal anhydrous silica Macrogol 400, pink iron oxide blend, yellow iron oxide blend dan purified water.*

Kapan dan Bagaimana Cara Penggunaan Telfast® 60 mg?

Usia	Dosis untuk rinitis alergi	Cara Pemakaian
Dewasa dan anak >12 tahun	1 tablet 2 kali sehari	 Konsumsi dengan air secukupnya, sebelum maupun sesudah makan.

Bagaimana Telfast® 60 mg Bekerja?

Telfast ® 60 mg memiliki **3 manfaat dalam 1 tablet:**

Beraksi 60 menit setelah pemberian. Fexofenadine HCl yang terkandung dalam Telfast® 60 mg merupakan antihistamin (anti-alergi) generasi ketiga yang bekerja spesifik pada reseptor H1 (reseptor histamin/alergi) untuk meredakan gejala rinitis alergi.

Tidak menyebabkan kantuk (bersifat non-sedatif).

Bekerja efektif 12 jam membantu mengatasi gejala rinitis alergi (gunakan sesuai dosis anjuran harian).

Apa yang Perlu Diperhatikan dalam Penggunaan Telfast® 60 mg?

Jangan gunakan Telfast® 60 mg:

Jika mengalami alergi terhadap Fexofenadine HCl atau bahan lain yang terkandung dalam obat ini.

Bersamaan dengan antibiotik eritromisin dan anti-jamur ketokonazol, maupun antasida yang mengandung magnesium & aluminium hidroklorida. Beri jarak 2 jam pada pemberiannya.

Pemberian Telfast® 60 mg pada orang tua dan pasien dengan gangguan ginjal atau hati harus diberikan dengan perhatian khusus.

Telfast® 60 mg tidak mempengaruhi kemampuan mengemudi atau mengoperasikan mesin.

Apa Efek Samping Telfast® 60 mg serta Penggunaannya pada Ibu Hamil dan Menyusui?

Penggunaan Telfast® 60 mg dalam kehamilan dan menyusui sebaiknya dihindari, kecuali atas petunjuk dokter.

Pada percobaan klinis terkontrol, Telfast® 60 mg dapat mempunyai efek samping berupa sakit kepala, mengantuk, mual, pusing, dan kelelahan. Efek samping ini mirip dengan yang dilaporkan pada kelompok kontrol (plasebo).

Pelaporan efek samping

Segera laporkan apabila Anda mengalami keluhan efek samping atau kondisi tidak nyaman selama dan setelah penggunaan obat kepada farmakovigilans@kalventis.com. Anda dapat membantu memberikan informasi terkait keamanan obat ini.

Tidak terdapat gejala spesifik overdosis yang dilaporkan terjadi hingga saat ini. Gejala yang muncul sesuai dengan gejala efek samping Telfast® 60 mg. Jika mengalami gejala-gejala tersebut, segera berkonsultasi ke dokter.

Kemasan & Cara Penyimpanan

Kemasan

Tablet salut selaput 60 mg
Dus berisi 1 blister @ 10 tablet

Reg. No. DTL1121205217A1

Penyimpanan

Simpan di bawah suhu 30°C

P. No. 1
Awas! Obat Keras
Bacalah aturan memakainya

HALAL INDONESIA ID00310000161080721

DISETUJUI OLEH BPOM : 22/12/2025

ID : EREG10002212500191

Diproduksi oleh:
PT Kalventis Sinergi Farma
Jakarta, Indonesia

Di bawah lisensi dari:
Opella Healthcare International SAS, France

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