TELFAST®
Fexofenadine HCl 120 mg

Composition
Each film coated tablet contains 112 mg of the active ingredient fexofenadine (as 120 mg of fexofenadine hydrochloride). The tablets also contain microcrystalline cellulose, pregelatinized maize starch, croscarmellose sodium, magnesium stearate, hypromellose, povidone, titanium dioxide (E 171), colloidal anhydrous silica, macrogol 400 and iron oxide (E 172).

Product Description
Peach, oval, double convex, tablet "012" on one side, blank on the other side.

Properties
Pharmacodynamic
Fexofenadine hydrochloride is a non-sedating H_1 antihistamine. Fexofenadine is a pharmacologically active metabolite of terfenadine.
Human histamine wheal and flare studies following single and twice daily doses of fexofenadine hydrochloride demonstrate that the drug exhibits an antihistaminic effect beginning within one hour, achieving maximum at 6 hours and lasting 24 hours. There was no evidence of tolerance to these effects after 28 days of dosing. A positive dose-response relationship between doses of 10 mg to 130 mg taken orally was found to exist. In this model of antihistaminic activity, it was found that doses of at least 130 mg were required to achieve a consistent effect that was maintained over a 24-hour period.
Maximum inhibition in skin wheal and flare areas were greater than 80 %. Clinical studies conducted in allergic rhinitis have shown that a dose of 120 mg is sufficient for 24-hour efficacy.
No significant differences in QTc intervals were observed in seasonal allergic rhinitis patients given fexofenadine hydrochloride up to 240 mg twice daily for 2 weeks when compared to placebo. Also, no significant change in QTc intervals was observed in healthy subjects given fexofenadine hydrochloride up to 60 mg twice daily for 6 months, 400 mg twice daily for 6.5 days and 240 mg once daily for 1 year, when compared to placebo. Fexofenadine at concentrations 32 times greater than the therapeutic concentration in man had no effect on the delayed rectifier K^+ channel cloned from human heart.
Fexofenadine hydrochloride (5-10 mg/kg po) inhibited antigeninduced bronchospasm in sensitized guinea pigs and inhibited histamine release at supratherapeutic concentrations (10 - 100 um) from peritoneal mast cells.

Pharmacokinetic
Fexofenadine hydrochloride is rapidly absorbed into the body following oral administration, with Tmax occurring at approximately 1-3 hours post dose. The mean Cmax value was approximately 427 ng/ml following the administration of a 120 mg dose once daily.
Fexofenadine is 60-70% plasma protein bound. Fexofenadine undergoes negligible metabolism, (hepatic or non-hepatic) as it was the only major compound identified in urine and feces of animals and man. The plasma concentration profiles of fexofenadine follow a biexponential decline with a terminal elimination half-life ranging from 11 to 15 hours after multiple dosing. The single and multiple dose pharmacokinetics of fexofenadine are linear for oral doses up to 120 mg BID. A dose of 240 mg BID produced slightly greater than proportional increase (8.8%) in steady state area under the curve, indicating that fexofenadine pharmacokinetics are practically linear at these doses. The major route of elimination is believed to be via biliary excretion while up to 10% of ingested dose is excreted unchanged through the urine.

Preclinical safety data
Dogs tolerated 450 mg/kg administered twice daily for 6 months and showed no toxicity other than occasional emesis. Also, in single dose dog and rodent studies, no treatment related gross findings were observed following necropsy.
Radiolabelled fexofenadine hydrochloride in tissue distribution studies of the rat indicated that fexofenadine did not cross the blood brain barrier.
Fexofenadine hydrochloride was found to be non-mutagenic in various in vitro and in vivo mutagenicity tests. The carcinogenic potential of fexofenadine hydrochloride was assessed using terfenadine studies with supporting pharmacokinetic studies showing fexofenadine hydrochloride exposure (via plasma AUC values). No evidence of carcinogenicity was observed in rats and mice given terfenadine (up to 150mg/kg/day).

In a reproductive toxicity study in mice, fexofenadine hydrochloride did not impair fertility, was not teratogenic and did not impair pre- or postnatal development.

Indications and usage
TELFAST 120 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 120 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.

Fertility, Pregnancy and lactation
Pregnancy
There are no adequate data from the use of fexofenadine hydrochloride in pregnant women.

Limited animal studies do not indicate direct or indirect harmful effects with respect to effects on pregnancy, embryonal/foetal development, Data).

Fexofenadine hydrochloride should not be used during pregnancy unless clearly necessary.

Breast-feeding
There are no data on the content of human milk after administering fexofenadine hydrochloride. However, when terfenadine was administered to nursing mothers fexofenadine was found to cross into human breast milk. Therefore fexofenadine hydrochloride is not recommended for mothers breast-feeding their babies.

Fertility
No human data on the effect of fexofenadine hydrochloride on fertility are available. In mice, there was no effect on fertility with fexofenadine hydrochloride treatment (see Preclinical Safety Data).

Effects on ability to drive and use machines
On the basis of the 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, Telfast 120 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 or performing complicated tasks.

Adverse reactions
In controlled clinical trials, the most commonly reported adverse events were headache, drowsiness, nausea, dizziness and fatigue. The incidence of these events observed with fexofenadine was similar to that observed with placebo.

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.

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 aluminium and 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.

Dosage and method of administration
Adults and children aged 12 years and over

The recommended dose of Telfast 120 is one tablet once daily.

Children under 12 years of age
The efficacy and safety of fexofenadine hydrochloride has not been studied in children under 12.

Special risk groups
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.

Overdosage
There has been no reported case of an acute overdose of fexofenadine hydrochloride. Standard measures should be considered to remove any unabsorbed drug. Haemodialysis does not effectively remove fexofenadine hydrochloride from blood.

Storage
Store TELFAST 120 film coated tablets at temperature below 30°C.

Presentation
Box contains 1 blisters x 10 film coated tablets
Reg.No.

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

Manufactured by:
PT Kalventis Sinergi Farma,
Jakarta, Indonesia

Under license from:
Opella Healthcare International SAS,
France

HALAL INDONESIA ID00310000161080721

Revision date: 30 April 2025

Opella.

Telfast®
Fexofenadine HCl **120 mg**

Apa itu Telfast® 120 mg?

Telfast® 120 mg mengandung Fexofenadine HCl, (antihistamin/anti-alergi generasi ketiga) yang efektif meringankan gejala rinitis alergi seperti bersin, pilek, gatal hidung/langit-langit mulut/ tenggorokan, mata merah/berair/gatal.

Sediaan Telfast® 120 mg	Kekuatan	Deskripsi Produk
Tablet salut selaput	120 mg	Tablet berwarna *peach*, berbentuk lonjong dan cembung di kedua sisi, satu sisi terdapat tanda "012" dan sisi lainnya polos.

Zat tambahan: *microcrystalline cellulose, pregelatinized maize starch, croscarmellose sodium, magnesium stearate, hypromellose, povidone, titanium dioxide (E 171), iron oxide yellow, silica colloidal anhydrous, iron oxide red, macrogol 400, purified water.*

Kapan dan Bagaimana Cara Penggunaan Telfast® 120 mg?

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

Bagaimana Telfast® 120 mg Bekerja?

Telfast ® 120 mg memiliki **3 manfaat dalam 1 tablet:**

Beraksi 60 menit setelah pemberian. Fexofenadine HCl yang terkandung dalam Telfast® 120 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 24 jam membantu mengatasi gejala rinitis alergi (gunakan sesuai dosis anjuran harian).

Apa yang Perlu Diperhatikan dalam Penggunaan Telfast® 120 mg ?

Jangan gunakan Telfast® 120 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® 120 mg pada orang tua dan pasien dengan gangguan ginjal atau hati harus diberikan dengan perhatian khusus.

Telfast® 120 mg tidak mempengaruhi kemampuan mengemudi atau mengoperasikan mesin.

Apa Efek Samping Telfast® 120 mg serta Penggunaannya pada Ibu Hamil dan Menyusui?

Penggunaan Telfast® 120 mg dalam kehamilan dan menyusui sebaiknya dihindari, kecuali atas petunjuk dokter.

Pada percobaan klinis terkontrol, Telfast® 120 mg dapat mempunyai efek samping berupa sakit kepala, mengantuk, mual, pusing, dan kelelahan. Kejadian ini mirip dengan yang teramati 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® 120 mg. Jika mengalami gejala-gejala tersebut, segera berkonsultasi ke dokter.

Kemasan & Cara Penyimpanan

Kemasan

Tablet salut selaput 120 mg
Dus berisi 1 blister @10 tablet salut selaput
Reg. No.

Penyimpanan

Simpan di bawah suhu 30°C

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

Diproduksi oleh:
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Di bawah lisensi dari:
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