FEXIGRA Oral Suspension (Fexofenadine hydrochloride)

Qualitative and Quantitative Composition

FEXIGRA Oral Suspension

Each 5 mL (one teaspoonful) contains:

Fexofenadine Hydrochloride IP..... 30 mg

In a flavoured syrup base

Colour: Titanium Dioxide IP

Dosage Form(S) and Strength(S)

Each 5 mL of suspension contains fexofenadine hydrochloride 30 mg

Clinical Particulars

Therapeutic Indications

Fexofenadine hydrochloride oral suspension is indicated for relief of symptoms associated with allergic rhinitis in children 2 to 11 years of age, and uncomplicated skin manifestations of chronic idiopathic urticaria in children 6 months to 11 years of age.

Posology and Method of Administration

Shake well before using. Use only with enclosed dosing cup.

Allergic Rhinitis

Children (2 to 11 years of age)

Recommended dose is 30 mg twice daily. A dose of 30 mg (5 mL in case of **FEXIGRA Oral Suspension**) once daily is recommended as the starting dose for paediatric patients with decreased renal function.

Adults and Children (aged 12 years and over)

Recommended dose is 120 mg once daily or 180 mg once daily. A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function.

Allergic Skin Conditions (e.g. Chronic Urticaria)

Children (6 months to 11 years of age)

Recommended dose is 30 mg (5 mL) twice daily for patients 2 to 11 years of age, and 15 mg (2.5 mL) twice daily for patients 6 months to less than 2 years of age.

For paediatric patients with decreased renal function, the recommended starting dose is 30 mg (5 mL) once daily for patients 2 to 11 years of age, and 15 mg (2.5 mL) once daily for patients 6 months to less than 2 years of age.

Adults and Children (aged 12 years and over)

Recommended dose is 180 mg once daily. A dose of 60 mg once daily is recommended as the starting dose in patients with decreased renal function.

Note: mL = millilitres

Contraindications

Fexofenadine suspension is contraindicated in patients with known hypersensitivity to any of the ingredients.

Drug Interactions

Co-administration of fexofenadine with erythromycin or ketoconazole resulted in no significant increases in QTc. Administration of an antacid containing aluminium or magnesium hydroxide gels should be 2 hours before or after administration of fexofenadine. No interaction between fexofenadine and omeprazole has been observed.

Drug Interaction with Erythromycin and Ketoconazole

Fexofenadine has been shown to exhibit minimal (ca. 5%) metabolism. However, co–administration of fexofenadine hydrochloride with either ketoconazole or erythromycin led to increased plasma concentrations of fexofenadine. Fexofenadine had no effect on the pharmacokinetics of either erythromycin or ketoconazole.

The mechanism of these interactions has been evaluated in *in vitro, in situ*, and *in vivo* animal models. These studies indicate that ketoconazole or erythromycin co-administration enhances fexofenadine gastrointestinal absorption. This observed increase in the bioavailability of fexofenadine may be due to transport-related effects, such as P-glycoprotein. *In vivo* animal studies also suggest that in addition to enhancing absorption, ketoconazole decreases fexofenadine gastrointestinal secretion, while erythromycin may also decrease biliary excretion.

Drug Interactions with Antacids

Administration of 120 mg of fexofenadine hydrochloride (2 × 60 mg capsule) within 15 minutes of an aluminium- and magnesium-containing antacid (Maalox®) decreased fexofenadine AUC by 41% and Cmax by 43%. Fexofenadine hydrochloride should not be taken closely in time with aluminium- and magnesium-containing antacids.

Interactions with Fruit Juices

Fruit juices such as grapefruit, orange and apple may reduce the bioavailability and exposure of fexofenadine. This is based on the results from three clinical studies using histamine-induced skin wheals and flares coupled with population pharmacokinetic analysis. The size of wheal and flare were significantly larger when fexofenadine hydrochloride was administered with either grapefruit

or orange juices compared with water. Based on the literature reports, the same effects may be extrapolated to other fruit juices such as apple juice. The clinical significance of these observations is unknown. In addition, based on the population pharmacokinetics analysis of the combined data from grapefruit and orange juices studies with the data from a bioequivalence study, the bioavailability of fexofenadine was reduced by 36%.

Use in Special Populations

Studies in special risk groups (elderly or hepatically impaired patients) indicate that it is not necessary to adjust the dose of fexofenadine hydrochloride in these patients. Used only if the potential benefit outweighs the potential risk.

Patients with Renal Impairment

In subjects with mild-to-moderate (creatinine clearance [CrCl] 41–80 mL/min) and severe (CrCl 11–40 mL/min) renal impairment, peak plasma concentrations of fexofenadine were 87% and 111% greater, respectively, and mean elimination half-lives were 59% and 72% longer, respectively, than observed in healthy subjects. Peak plasma concentrations in subjects on dialysis (CrCl ≤10 mL/min) were 82% greater and half-life was 31% longer than observed in healthy subjects. 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. For pediatric patients with decreased renal function, the recommended starting dose of fexofenadine is 30 mg once daily for patients 2 to 11 years of age, and 15 mg once daily for patients 6 months to less than 2 years of age.

Patients with Hepatic Impairment

The pharmacokinetics of fexofenadine in subjects with hepatic disease did not differ substantially from that observed in healthy subjects

Pregnant Women

Teratogenic Effects: Pregnancy Category C

There was no evidence of teratogenicity in rats or rabbits at oral doses of terfenadine up to 300 mg/kg (which led to fexofenadine exposures that were approximately 4 and 30 times, respectively, the exposure at the maximum recommended human daily oral dose of 180 mg of fexofenadine hydrochloride based on comparison of AUCs).

In mice, no adverse effects and no teratogenic effects during gestation were observed with fexofenadine hydrochloride at oral doses up to 3,730 mg/kg (which led to fexofenadine exposures that were approximately 15 times the exposure at the maximum recommended human daily oral dose of 180 mg of fexofenadine hydrochloride based on comparison of AUCs).

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 foetus.

Nonteratogenic Effects

Dose-related decreases in pup weight gain and survival were observed in rats exposed to an oral dose of 150 mg/kg of terfenadine (which led to fexofenadine exposures that were approximately 3 times the exposure at the maximum recommended human daily oral dose of 180 mg of fexofenadine hydrochloride based on comparison of AUCs).

Lactating Women

It is not known if fexofenadine is excreted in human milk. There are no adequate and well-controlled studies in women during lactation. Because many drugs are excreted in human milk, caution should be exercised when fexofenadine hydrochloride is administered to a nursing mother.

Paediatric Patients

The recommended doses in paediatric patients (6 months to 11 years of age) are based on a cross-study comparison of the pharmacokinetics of fexofenadine in adults and paediatric subjects and on the safety profile of fexofenadine hydrochloride in both adult and paediatric subjects at doses equal to or higher than the recommended doses.

The safety of fexofenadine hydrochloride at a dose of 30 mg twice daily has been demonstrated in 438 paediatric subjects (6 years to 11 years of age) in two placebo-controlled 2-week seasonal allergic rhinitis trials. The safety of fexofenadine hydrochloride at doses of 15 mg and 30 mg given once and twice a day has been demonstrated in 969 paediatric subjects (6 months to 5 years of age) with allergic rhinitis in three pharmacokinetic studies and three safety studies. The safety of fexofenadine hydrochloride for the treatment of chronic idiopathic urticaria in subjects (6 months to 11 years of age) is based on a cross-study comparison of the pharmacokinetics of fexofenadine hydrochloride in adult and paediatric subjects and on the safety profile of fexofenadine in both adult and pediatric subjects at doses equal to or higher than the recommended dose.

The effectiveness of fexofenadine hydrochloride for the treatment of seasonal allergic rhinitis in subjects (6 to 11 years of age) was demonstrated in 1 trial (n=411) in which fexofenadine hydrochloride tablets 30 mg twice daily significantly reduced total symptom scores compared with placebo, along with extrapolation of demonstrated efficacy in subjects aged 12 years and above, and the pharmacokinetic comparisons in adults and children. The effectiveness of fexofenadine hydrochloride 30 mg twice daily for the treatment of seasonal allergic rhinitis in patients (2 to 5 years of age) is based on the pharmacokinetic comparisons in adult and paediatric subjects and an extrapolation of the demonstrated efficacy of fexofenadine hydrochloride in adult subjects with this condition and the likelihood that the disease course, pathophysiology, and the drug’s effect are substantially similar in paediatric patients to those in adult patients. Administration of a 15 mg dose of fexofenadine hydrochloride to paediatric subjects (6 months to less than 2 years of age) and a 30 mg dose to paediatric subjects (2 to 11 years of age) produced exposures comparable with those seen with a dose of 60 mg administered to adults.

The safety and effectiveness of fexofenadine hydrochloride in paediatric patients under 6 months of age have not been established.

Geriatric Patients

This drug is known to be substantially excreted by the kidneys, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Effects on Ability to Drive and Use Machines

Based on the pharmacodynamic profile and reported adverse reactions, it is unlikely that fexofenadine hydrochloride will produce an effect on the ability to drive or use machines. In objective tests, fexofenadine 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 medicinal products, it is advisable to check the individual response before driving or performing complicated tasks.

Undesirable Effects

Seasonal Allergic Rhinitis

Adults

In placebo-controlled seasonal allergic rhinitis clinical trials in subjects 12 years of age and older, which included 2,461 subjects receiving fexofenadine hydrochloride capsules at doses of 20 mg to 240 mg twice daily, adverse events were similar in fexofenadine hydrochloride- and placebo-treated subjects. All adverse events that were reported by greater than 1% of subjects who received the recommended daily dose of fexofenadine hydrochloride (60 mg capsules twice daily), and that were more common with fexofenadine hydrochloride than placebo, are listed in Table 1.

In a placebo-controlled clinical study in the United States, which included 570 subjects aged 12 years and older receiving fexofenadine hydrochloride tablets at doses of 120 or 180 mg once daily, adverse events were similar in fexofenadine hydrochloride- and placebo-treated subjects. Table 1 also lists adverse experiences that were reported by greater than 2% of subjects treated with fexofenadine hydrochloride tablets at doses of 180 mg once daily and that were more common with fexofenadine hydrochloride than placebo.

The incidence of adverse events, including drowsiness, was not dose-related and was similar across subgroups defined by age, gender, and race.

Table 1: Adverse events in subjects aged 12 years and older reported in placebo-controlled seasonal allergic rhinitis clinical trials in the united states

Twice-daily dosing with fexofenadine hydrochloride tablets at rates of greater than 2%

Adverse Events	**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%
Dysmenorrhoea	1.5%	0.3%
Drowsiness	1.3%	0.9%
Dyspepsia	1.3%	0.6%
Fatigue	1.3%	0.9%

Once-daily dosing with fexofenadine hydrochloride tablets at rates of greater than 2%

Adverse Events	**Fexofenadine 180 mg Once Daily (n=283)**	**Placebo (n=293)**
Headache	10.6%	7.5%
Upper respiratory reaction	3.2%	3.1%

Back pain	2.8%	1.4%

The frequency and magnitude of laboratory abnormalities were similar in fexofenadine hydrochloride- and placebo-treated subjects.

Paediatric Patients

Table 2 lists adverse experiences in subjects aged 6 years to 11 years of age which were reported by greater than 2% of subjects treated with fexofenadine hydrochloride tablets at a dose of 30 mg twice daily in placebo-controlled seasonal allergic rhinitis studies in the United States and Canada that were more common with fexofenadine hydrochloride than placebo.

Table 2: Adverse events reported in placebo-controlled seasonal allergic rhinitis studies in paediatric subjects aged 6 years to 11 years in the united states and canada at rates greater than 2%

Adverse Events	**Fexofenadine 30 mg Twice Daily (n=209)**	**Placebo (n=229)**
Headache	7.2%	6.6%
Accidental injury	2.9%	1.3%
Coughing	3.8%	1.3%
Fever	2.4%	0.9%
Pain	2.4%	0.4%
Otitis media	2.4%	0.0%
Upper respiratory tract infection	4.3%	1.7%

Table 3 lists adverse events in subjects 6 months to 5 years of age in three open single- and multiple-dose pharmacokinetic studies and three placebo-controlled safety studies with fexofenadine hydrochloride capsule content (484 subjects) and suspension (50 subjects) at doses of 15 mg (108 subjects) and 30 mg (426 subjects) given twice a day.

Table 3: Adverse events reported in placebo-controlled studies in paediatric subjects with allergic rhinitis aged 6 months to 5 years of age at rates greater than 2%

Adverse Events	**Fexofenadine 15 mg Twice Daily (n=108)**	**Fexofenadine 30 mg Twice Daily (n=426)**	**Total (n=534)**	**Placebo (n=430)**
Vomiting	12.0%	4.2%	5.8%	8.6%
Pyrexia	1.9%	4.5%	3.9%	7.0%
Cough	1.9%	4.0%	3.6%	3.3%
Otitis media	2.8%	3.8%	3.6%	3.3%
Diarrhoea	3.7%	2.8%	3.0%	2.6%
Rhinorrhoea	0.9%	2.1%	1.9%	0.9%
Upper respiratory tract infection	0.9%	2.1%	1.9%	4.0%
Somnolence	2.8%	0.7%	1.1%	0.2%

Chronic Idiopathic Urticaria

Adverse events reported by subjects (12 years of age and older) in placebo-controlled chronic idiopathic urticaria studies were similar to those reported in placebo-controlled seasonal allergic rhinitis studies. In placebo-controlled chronic idiopathic urticaria clinical trials, which included 726 subjects (12 years of age and older) receiving fexofenadine hydrochloride tablets at doses of 20 to 240 mg twice daily, adverse events were similar in fexofenadine hydrochloride- and placebo-treated patients. Table 4 lists adverse experiences in subjects (aged 12 years and older), which were reported by greater than 2% of subjects treated with fexofenadine hydrochloride 60 mg tablets twice daily in controlled clinical studies in the United States and Canada and that were more common with fexofenadine hydrochloride than placebo.

In a placebo-controlled clinical study in the United States, which included 167 subjects (aged 12 years and older) receiving fexofenadine hydrochloride 180 mg tablets, adverse events were similar in fexofenadine hydrochloride- and placebo-treated subjects. Table 4 also lists adverse experiences that were reported by greater than 2% of subjects treated with fexofenadine hydrochloride tablets at doses of 180 mg once daily and that were more common with fexofenadine hydrochloride than placebo.

The safety of fexofenadine hydrochloride in the treatment of chronic idiopathic urticaria in paediatric patients (6 months to 11 years of age) is based on the safety profile of fexofenadine hydrochloride in adults and paediatric patients at doses equal to or higher than the recommended dose.

Table 4: Adverse events reported in subjects 12 years of age and older in placebo-controlled chronic idiopathic urticaria studies

Twice-daily dosing with fexofenadine hydrochloride in studies in the United States and Canada at rates greater than 2%

Adverse Events	**Fexofenadine 60 mg Twice Daily (n=191)**	**Placebo (n=183)**
Dyspepsia	4.7%	4.4%
Myalgia	2.6%	2.2%
Back pain	2.1%	1.1%
Dizziness	2.1%	1.1%
Pain in extremity	2.1%	0.0%

Once-daily dosing with fexofenadine hydrochloride in a study in the United States at rates greater than 2%

Adverse Events	**Fexofenadine 180 mg Once Daily (n=167)**	**Placebo (n=92)**
Headache	4.8%	3.3%
Nasopharyngitis	2.4%	2.2%
Upper respiratory tract infection	2.4%	2.2%

Events that have been reported during controlled clinical trials involving seasonal allergic rhinitis and chronic idiopathic urticaria subjects, with incidence less than 1% and similar to placebo and have been rarely reported during postmarketing surveillance, include the following: insomnia, nervousness, and sleep disorders or paroniria. In rare cases, rash, urticaria, pruritus and hypersensitivity reactions with manifestations such as angio-oedema, chest tightness, dyspnoea, flushing, and systemic anaphylaxis have been reported.

Reporting of Side Effects

If you experience any side effects, talk to your doctor or pharmacist or write to drugsafety@cipla.com. You can also report side effects directly via the National Pharmacovigilance Programme of India by calling on **1800 180 3024** or report to Cipla Ltd. on **1800 267 7779**. By reporting side effects, you can help provide more information on the safety of this product.

Overdose

Reports of fexofenadine hydrochloride overdose have been infrequent and contain limited information. However, dizziness, drowsiness, and dry mouth have been reported. Single doses of fexofenadine hydrochloride up to 800 mg (6 healthy subjects at this dose level), and doses up to 690 mg twice daily for 1 month (3 healthy subjects at this dose level) or 240 mg once daily for 1 year (234 healthy subjects at this dose level) were administered without the development of clinically significant adverse events as compared with placebo.

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

No deaths occurred at oral doses of fexofenadine hydrochloride up to 5,000 mg/kg in mice (110 times the maximum recommended daily oral dose in adults and children based on mg/m2) and up to 5,000 mg/kg in rats (230 times the maximum recommended daily oral dose in adults and 210 times the maximum recommended daily oral dose in children based on mg/m^2). 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 2,000 mg/kg (300 times the maximum recommended daily oral dose in adults and 280 times the maximum recommended daily oral dose in children based on mg/m^2).

Pharmacological Properties

Mechanism of Action

Fexofenadine hydrochloride, the major active metabolite of terfenadine, is an antihistamine with selective peripheral H_1-receptor antagonist activity.

Both enantiomers of fexofenadine hydrochloride displayed approximately equipotent antihistaminic effects. Fexofenadine hydrochloride inhibited antigen-induced bronchospasm in sensitised guinea pigs and histamine release from peritoneal mast cells in rats. The clinical significance of these findings is unknown. In laboratory animals, no anticholinergic or alpha1-adrenergic blocking effects were observed. Moreover, no sedative or other central nervous system effects were observed. Radiolabelled tissue distribution studies in rats indicated that fexofenadine does not cross the blood-brain barrier.

Pharmacodynamic Properties

Wheal and Flare

Human histamine skin wheal and flare studies following single and twice-daily doses of 20 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. The clinical significance of these observations is unknown.

Histamine skin wheal and flare studies in subjects 7 to 12 years of age showed that following a single dose of 30 or 60 mg, antihistamine effect was observed at 1 hour and reached a maximum by 3 hours. Greater than 49% inhibition of wheal area, and 74% inhibition of flare area were maintained for 8 hours following the 30 mg and 60 mg dose.

Effects on QT_c

In dogs (30 mg/kg/orally twice daily for 5 days) and rabbits (10 mg/kg, intravenously over 1 hour), fexofenadine hydrochloride did not prolong QTc. In dogs, the plasma fexofenadine concentration was approximately 9 times the therapeutic plasma concentrations in adults receiving the maximum recommended human daily oral dose of 180 mg. In rabbits, the plasma fexofenadine concentration was approximately 20 times the therapeutic plasma concentration in adults receiving the maximum recommended human daily oral dose of 180 mg. No effect was observed on calcium channel current, delayed K+ channel current, or action potential duration in guinea pig myocytes, or on the delayed rectifier K+ channel cloned from human heart at concentrations up to 1 × 10-5 M of fexofenadine.

No statistically significant increase in mean QTc interval compared with placebo was observed in 714 subjects with seasonal allergic rhinitis given fexofenadine hydrochloride capsules in doses of 60–240 mg twice daily for 2 weeks. Paediatric subjects from two placebo-controlled trials (n=855) treated with up to 60 mg fexofenadine hydrochloride twice daily demonstrated no significant treatment- or dose-related increases in QTc.

In addition, no statistically significant increase in mean QTc interval compared with placebo was observed in 40 healthy subjects given fexofenadine hydrochloride as an oral solution at doses up to 400 mg twice daily for 6 days, or in 230 healthy subjects given fexofenadine hydrochloride 240 mg once daily for 1 year. In subjects with chronic idiopathic urticaria, there were no clinically relevant differences for any ECG intervals, including QTc, between those treated with fexofenadine hydrochloride 180 mg once daily (n=163) and those treated with placebo (n=91) for 4 weeks.

Pharmacokinetic Properties

The pharmacokinetics of fexofenadine hydrochloride in subjects with seasonal allergic rhinitis and subjects with chronic urticaria were similar to those in healthy subjects.

Absorption

Following oral administration of a 30 mg dose of Fexofenadine hydrochloride to healthy adult subjects, the mean C_{max} was 118.0 ng/mL and occurred at approximately 1.0 hour. The administration of 30 mg Fexofenadine hydrochloride with a high-fat meal decreased the AUC and the mean C_{max} by approximately 30 and 47%, respectively, in healthy adult subjects.

Distribution

Fexofenadine hydrochloride is 60–70% bound to plasma proteins, primarily albumin, and α_1-acid glycoprotein.

Metabolism

Approximately 5% of the total dose of fexofenadine hydrochloride was eliminated by hepatic metabolism.

Elimination

The mean elimination half-life of fexofenadine was 14.4 hours following administration of 60 mg twice daily in healthy subjects.

Human mass balance studies documented a recovery of approximately 80% and 11% of the [14C] fexofenadine hydrochloride dose in the faeces and urine, respectively. Because the absolute bioavailability of fexofenadine hydrochloride has not been established, it is unknown if the faecal component represents primarily unabsorbed drug or the result of biliary excretion.

Non-Clinical Properties

Animal toxicology or pharmacology

Carcinogenesis, Mutagenesis, Impairment of Fertility

The carcinogenic potential of fexofenadine was assessed using terfenadine studies with adequate fexofenadine exposure (based on plasma area-under-the-concentration vs time [AUC] values). No evidence of carcinogenicity was observed in an 18-month study in mice and in a 24-month study in rats at oral doses up to 150 mg/kg of terfenadine (which led to fexofenadine exposures that were approximately 3 and 5 times the exposure at the maximum recommended daily oral dose of fexofenadine hydrochloride in adults [180 mg] and children [60 mg], respectively).

In *in vitro* (Bacterial Reverse 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 an oral dose of 150 mg/kg of terfenadine (which led to fexofenadine exposures that were approximately 3 times the exposure at the maximum recommended human daily oral dose of 180 mg of fexofenadine hydrochloride based on comparison of AUCs). In mice, fexofenadine hydrochloride produced no effect on male or female fertility at average oral doses up to 4438 mg/kg (which led to fexofenadine exposures that were approximately 13 times the exposure at the maximum recommended human daily oral dose of 180 mg of fexofenadine hydrochloride based on comparison of AUCs).

Description

Fexofenadine hydrochloride, the active ingredient in FEXIGRA Oral Suspension, is a histamine H1 receptor antagonist with the chemical name (±)-4-[1 hydroxy-4-[4-(hydroxydiphenylmethy-)-1-piperidinyl]-butyl]-α, α-dimethyl benzeneacetic acid hydrochloride. 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.

Pharmaceutical Particulars

Incompatibilities

Not applicable.

Shelf-Life

As on the pack

Packaging information

FEXIGRA Oral Suspension ..... Each bottle contains 100 mL of suspension

Storage and Handling Instructions

Store at a temperature not exceeding 30ºC. Protect from light and moisture. Keep out of the reach of children.

Patient Counselling Information

● What is FEXIGRA Oral Suspension?

FEXIGRA Oral Suspension contains fexofenadine hydrochloride, which is a histamine H_1 receptor antagonist. It is indicated for the relief of symptoms associated with allergic rhinitis in children 2 to 11 years of age, and uncomplicated skin manifestations of chronic idiopathic urticaria in children 6 months to 11 years of age.

Do not take if you have an allergy to this drug

The products should not be used by patients who are hypersensitive to any of the ingredients.

Before you take FEXIGRA Oral Suspension, tell your HCP about other medications

If you are taking, have recently taken or might take any other medicine:

- Erythromycin (an antibiotic)
- Ketoconazole (a treatment for fungal infections)
- Indigestion remedies containing aluminum and magnesium may affect the action of fexofenadine hydrochloride by lowering the amount of medicinal product absorbed. It is recommended that you leave about 2 hours between the time that you take fexofenadine hydrochloride oral suspension and your indigestion remedy.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take fexofenadine hydrochloride if you are pregnant, unless necessary. Fexofenadine

hydrochloride oral suspension is not recommended during breast-feeding.

Driving and using machines

Fexofenadine hydrochloride oral suspension is unlikely to affect your ability to drive or operate machinery. However, you should check whether taking this suspension makes you feel sleepy or dizzy before driving or operating machinery.

● How to take FEXIGRA Oral Suspension

Patients and parents/carers of paediatric patients should be advised to shake the **FEXIGRA Oral Suspension** bottle well before each use. Use only with the enclosed dosing cup.

Allergic rhinitis

Children (2 to 11 years of age)

Recommended dose is 30 mg (5 mL) twice daily.

Allergic skin conditions (e.g. chronic urticaria)

Children (6 months to 11 years of age)

Recommended dose is 30 mg (5 mL) twice daily for patients 2 to 11 years of age, and 15 mg (2.5 mL) twice daily for patients 6 months to less than 2 years of age.

Note: mL = millilitres

Check with your doctor about dosage for

- Adults 65 years of age and older
- Patients with kidney disease

Patients should be instructed to take **FEXIGRA Oral Suspension** only as prescribed. **Do not exceed the recommended dose.**

● What are the possible side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you get any of the following symptoms after taking this suspension, you should contact your doctor or pharmacist immediately as these may be signs of a serious allergic reaction: swelling of the face, lips, tongue or throat and difficulty breathing.

The following side effects have also been reported:

- Common (may affect up to 1 in 10 people)
  - Headache
  - Drowsiness
  - Feeling sick (nausea)
  - Dizziness
- Uncommon (may affect up to 1 in 100 people)

- Tiredness or sleepiness

- Not known (frequency cannot be estimated from the available data)
  - Difficulty sleeping (insomnia)
  - Sleeping disorders
  - Bad dreams
  - Nervousness
  - Fast or irregular heartbeat
  - Diarrhea
  - Skin rash and itching
  - Hives
  - Serious allergic reaction, which can cause swelling of the face, lips, tongue or throat
  - Difficulty breathing

Reporting of side effects

If you experience any side effects, talk to your doctor or pharmacist or write to drugsafety@cipla.com. You can also report side effects directly via the National Pharmacovigilance Programme of India by calling on **1800 180 3024** or report to Cipla Ltd. on **1800 267 7779**. By reporting side effects, you can help provide more information on the safety of this product.

● How to store FEXIGRA Oral Suspension

Do not take this medicine after the expiry date, which is stated on the blister and carton after EXP. The expiry date refers to the last day of the month. Protect from light. Keep out of the reach of children.

● General information about the safe and effective use of this drug

Tell your doctor before taking **FEXIGRA Oral Suspension** if you have

- problems with your liver or kidneys
- are elderly
- have heart problems, as fexofenadine, like other antihistamines, may cause your heart to beat faster (tachycardia) or you can feel your heart beating rapidly and irregularly (palpitations).

● What are the ingredients?

Each 5 mL (one teaspoonful) of **FEXIGRA Oral Suspension** contains fexofenadine hydrochloride 30 mg in a flavoured syrup base.

Details of the Manufacturers

Mfd. By Cipla Ltd.

Registered Office:

Cipla House, Peninsula Business Park,

Ganpatrao Kadam Marg

Lower Parel

Mumbai – 400 013, India

Details of Permission or License Number with Date

M.L. MNB/16/970 dated 10/03/17

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