KEEP ALLERGY AWAY

ACTOVERCO

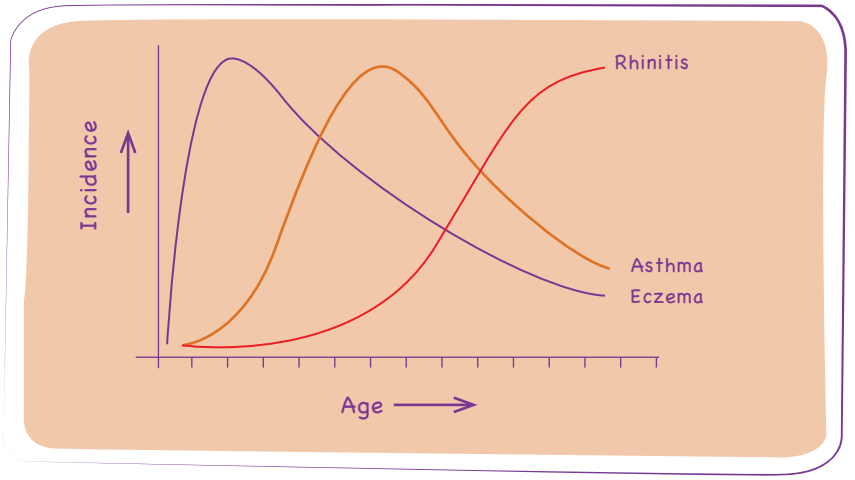
Together for a healthy future

fastover

Tablets 30, 120, 180 mg

FEXOFENADINE

Allergic rhinitis (AR) is the most common chronic disease in the pediatric population and its prevalence is increasing[1]

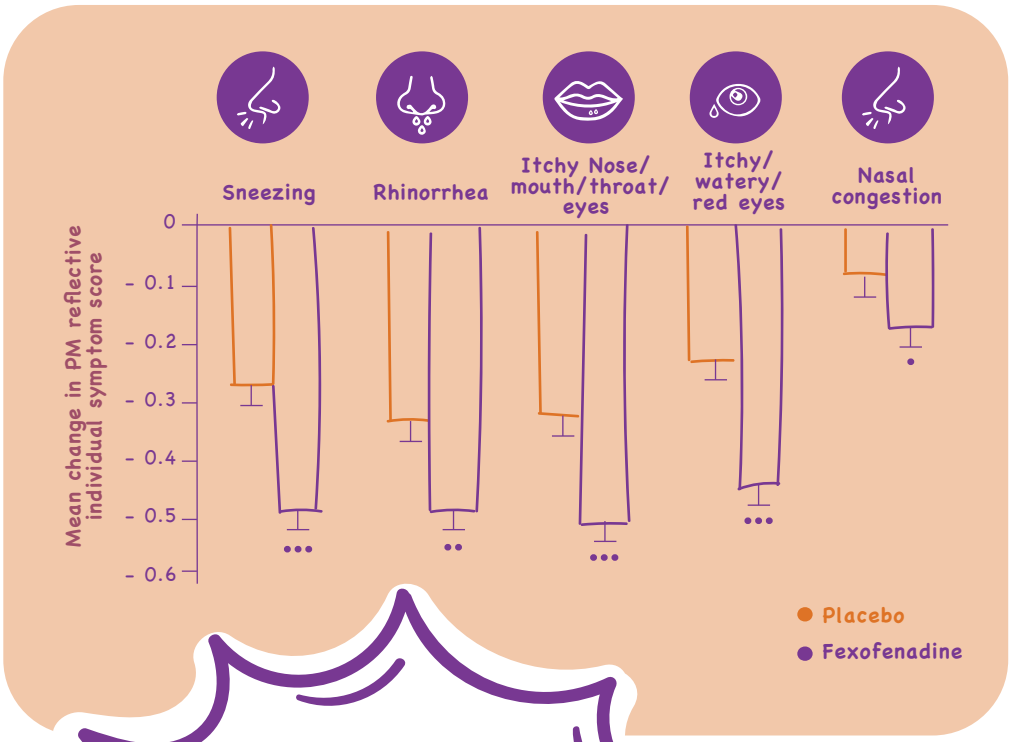


The atopic march. The incidence of atopic disease varies with age, with rhinitis incidence increasing during school years

The prevalence of allergic rhinitis slowly increased over time from **3% to 15%**[1]

In the general population, **10–15%** of children will be atopic[1]

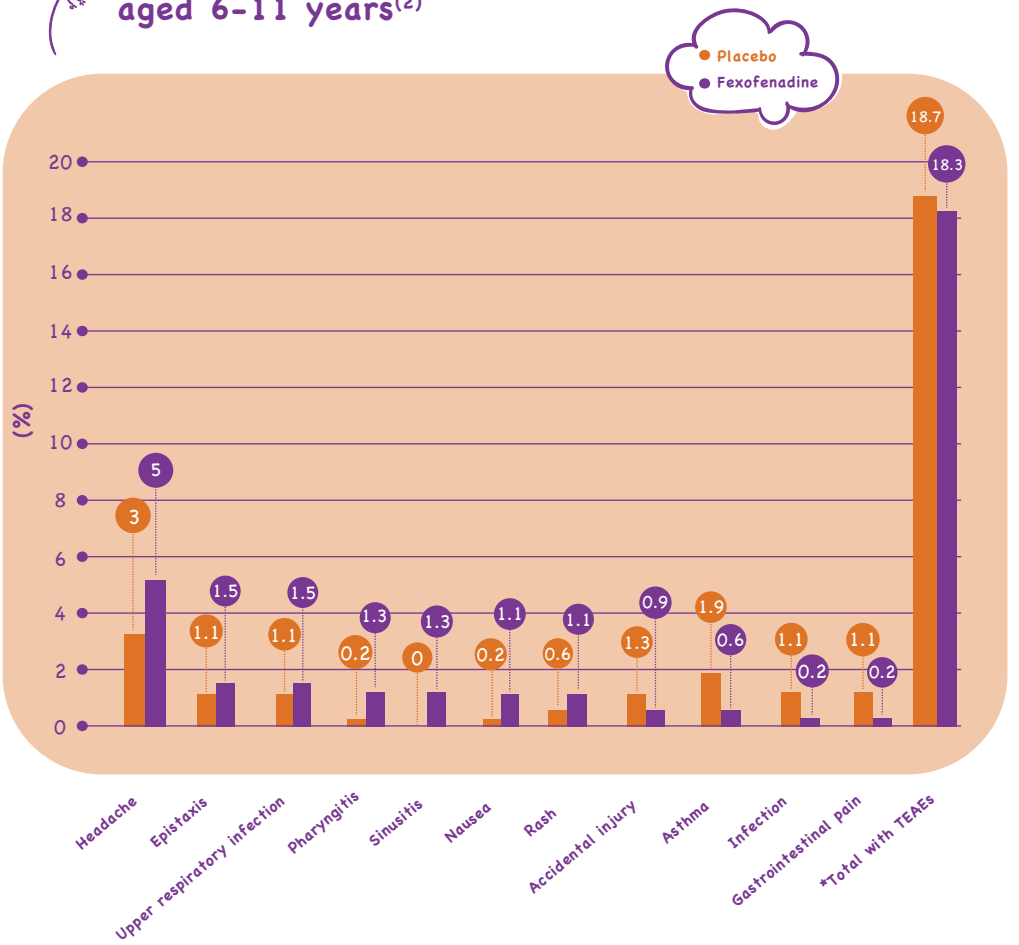
Fexofenadine relieves all symptoms of allergic rhinitis in children aged 6-11 years[2]



The results of this study demonstrate that fexofenadine HCl (30 mg bid) is effective in reducing both the TSS and individual symptom scores of SAR compared with placebo[1]

TSS: Total Severity Score
SAR: Seasonal allergic rhinitis

Fexofenadine is safe and well-tolerated in children aged 6-11 years[2]



Fexofenadine Safety in children aged 6 –11 years showed a **similar incidence of adverse effects to placebo**[2]

Fexofenadine has **no effect on QTc compared with placebo**[2]

The pharmacokinetics and pharmacologic effects of fexofenadine in children are similar to those in adults[2]

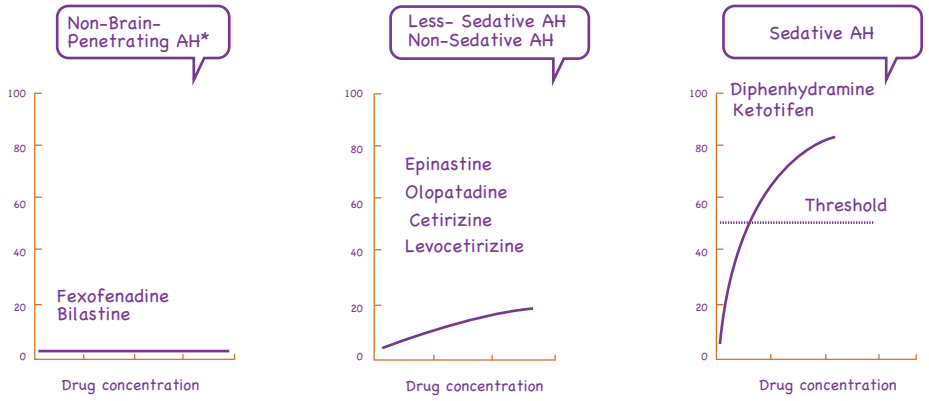
fastover
Tablets 30, 120, 180 mg FEXOFENADINE

Does not cause cognitive or psychomotor impairment[3]

Has a long-lasting effect on histamine-induced wheal[2,3]

Suppress histamine-induced wheal and flare within 1 to 2 hours in children[2,3]

Fexofenadine doesn't penetrate the blood-brain barrier (BBB) called "non-brain-penetrating antihistamine" [4]



*Ah: Antihistamine

Fexofenadine shows an increased specificity for the H1 receptor, is less likely to cross the blood-brain barrier, and is associated with fewer anticholinergic and central nervous system effects [3]

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Prescribing information:

• **Name of the medicinal product:** Fastover 30 , 60 , 120, 180 mg film-coated tablets.

• **Therapeutic indications:** Fastover 30 mg and 60 mg are indicated in children 6-11 years of age for the relief of symptoms associated with seasonal allergic rhinitis.

• **Posology and method of administration:**

• For Allergic symptoms/rhinitis: Oral: Children 2 to 11 years:30 mg twice daily . Children ≥12 years and Adolescents: Tablets, orally disintegrating tablet (ODT): 60 mg twice daily

• For Chronic idiopathic urticaria: oral: Children 2 to 11 years: orally disintegrating tablet (ODT): 30 mg twice daily. Children ≥12 years and Adolescents: Tablets, orally disintegrating tablet (ODT): 60 mg twice daily

• **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. The efficacy and safety of fexofenadine hydrochloride 120 mg has not been studied in children under 12.

• **Special warnings and precautions for use:** As with most new medicinal products 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. Patients with a history of or ongoing cardiovascular disease should be warned that, antihistamines as a medicine class, have been associated with the adverse reactions, tachycardia and palpitations.

• **Dose adjustment in Renal Impairment for Pediatric:** Infants ≥ 6 months to Children <2 years: Any degree of renal impairment: Initial: 15 mg once daily

Children 2 to 11 years: Any degree of renal impairment: 30 mg once daily

Children ≥12 years and Adolescents: 60 mg once daily

Others have suggested the following: Children ≥12 years and Adolescents

- CrCl 10 to 50 mL/minute: 60 mg once daily

- CrCl <10 mL/minute: 30 mg once daily

Hemodialysis: Not effectively removed by hemodialysis: 30 mg once daily

Peritoneal dialysis: 30 mg once daily

• **Dosing Hepatic Impairment for Pediatric:**
There are no dosage adjustments provided in manufacturer's labeling.

• **Interaction:** Erythromycin, ketoconazole , antacids containing aluminum and magnesium hydroxide . it is advisable to leave 2 hours between administration of fexofenadine.

• **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/fetal development, parturition or postnatal development. 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.

• **Effects on ability to drive and use machines:** On the basis of the pharmacodynamic profile and reported adverse reactions 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 medicinal products, it is advisable to check the individual response before driving or performing complicated tasks.

• **Undesirable effects:** common: headache, drowsiness, dizziness, Nausea. Uncommon: fatigue.

• **post-marketing undesirable effects:** hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnoea, flushing and systemic anaphylaxis
insomnia, nervousness, sleep disorders or nightmares/
excessive dreaming (paranoia), tachycardia, palpitations, diarrhea, rash, urticaria, pruritus[5]

References:
1. Meltzer EO, editor Allergic rhinitis: managing the pediatric spectrum. Allergy and asthma proceedings; 2006: OceanSide Publications, Inc.
2. Wahn U, Meltzer EO, Finn Jr AF, Kowalski ML, Decosta P, Hedlin G, et al. Fexofenadine is efficacious and safe in children (aged 6–11 years) with seasonal allergic rhinitis. 2003;111(4):763-9.
3. Kamei H, Isaji A, Noda Y, Ishikawa K, Senzaki K, Yamada K, et al. Effects of single therapeutic doses of promethazine, fexofenadine and olopatadine on psychomotor function and histamine-induced wheal-and flare-responses: a randomized double-blind, placebo-controlled study in healthy volunteers. 2012;304(4):263-72.
4. Kawauchi H, Yanai K, Wang D-Y, Itahashi K, Okubo KJIjoms. Antihistamines for allergic rhinitis treatment from the viewpoint of nonsedative properties. 2019;20(1):213
5. fexofenadine pediatric drug information wolters kluwer; 2019.

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