

CHILDRENS FEXOFENADINE HYDROCHLORIDE ALLERGY- fexofenadine hydrochloride suspension
Taro Pharmaceuticals U.S.A., Inc.

Children's Fexofenadine Hcl Allergy

Drug Facts

Active ingredient (in each 5 mL)

Fexofenadine HCl 30 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

Warnings

Do not use if you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have kidney disease. Your doctor should determine if you need a different dose.

When using this product

- do not take more than directed
- do not take at the same time as aluminum or magnesium antacids
- do not take with fruit juices (see Directions)

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- shake well before using
- use only with enclosed dosing cup

adults and children 12 years of age and over	take 10 mL every 12 hours; do not take more than 20 mL in 24 hours
children 2 to under 12 years of age	take 5 mL every 12 hours; do not take more than 10 mL in 24 hours
children under 2 years of age	ask a doctor
adults 65 years of age and older	ask a doctor
consumers with kidney disease	ask a doctor

Note: mL = milliliters

Other information

- each 5 mL contains: **sodium 14 mg**
- safety sealed: do not use if carton is opened, or if imprinted safety seal is broken or missing.
- store between 20° and 25°C (68° and 77°F)

Inactive ingredients

artificial raspberry flavor, edetate disodium, maltitol solution, poloxamer 407, potassium sorbate, propylene glycol, purified water, sodium benzoate, sodium phosphate dibasic heptahydrate, sodium phosphate monobasic monohydrate, sucralose powder, titanium dioxide and xanthan gum

Questions?

Call **1-866-923-4914**

Distributed by:

Taro Pharmaceuticals U.S.A., Inc.

Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 120 mL Bottle Carton

NDC 51672-2141-8

Compare to the active ingredient in Children's Allegra® Allergy*

Children's Allergy

Fexofenadine HCl
Oral Suspension,
30 mg/ 5 mL
Antihistamine

NON-DROWSY

12
Hour

Berry Flavor

2
Years
& Older

INDOOR/OUTDOOR
ALLERGY RELIEF

- ✓ Sneezing
- ✓ Runny Nose
- ✓ Itchy, Watery Eyes
- ✓ Itchy Nose or Throat

Dye free / Alcohol free / Sugar free

LIQUID
Oral Suspension

4 fl. oz.
(120 mL)



CHILDRENS FEXOFENADINE HYDROCHLORIDE ALLERGY

fexofenadine hydrochloride suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2141
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	30 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength
edetate disodium (UNII: 7FLD91C86K)	
maltitol (UNII: D65DG142WK)	
poloxamer 407 (UNII: TUF2IVW3M2)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70WT22SF4B)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
sucralose (UNII: 96K6UQ3ZD4)	
potassium sorbate (UNII: 1VPU26JZZ4)	
titanium dioxide (UNII: 15FIX9V2JP)	
xanthan gum (UNII: TTV12P4NEE)	
sodium benzoate (UNII: OJ245FE5EU)	

Product Characteristics			
Color	WHITE (white to off-white)	Score	
Shape		Size	
Flavor	RASPBERRY	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2141-8	1 in 1 CARTON	01/24/2024	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:51672-2141-1	1 in 1 CARTON	01/24/2024	
2		240 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208123	01/24/2024	

Labeler - Taro Pharmaceuticals U.S.A., Inc. (145186370)

