

**FEXOFENADINE HYDROCHLORIDE - fexofenadine hydrochloride
oral suspension
Aurohealth LLC**

Fexofenadine Hydrochloride Oral Suspension 30 mg/5 mL

Drug Facts

Active ingredient (in each 5 mL)

Fexofenadine Hydrochloride USP 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 (1-800-222-1222) 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: **phosphorus 15 mg and sodium 18 mg**
- safety sealed: do not use if carton is opened or seal under cap opening is broken or missing
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

art strawberry flavor, dibasic sodium phosphate anhydrous, edetate disodium, ethylparaben, methylparaben, modified food starch (corn), monobasic sodium phosphate, poloxamer 407, propylene glycol, purified water, sucrose, titanium dioxide, triacetin, xanthan gum, xylitol.

Questions or comments?

call **1-855-274-4122** (Monday - Friday 8:30 AM to 5:00 PM EST)

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: AP/DRUGS/04/2016

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 8 fl. oz.(240 mL Bottle) Container Label

AUROHEALTH

NDC 58602-426-20

Ages 2 Years & Older

NON-DROWSY

Children's

Fexofenadine Hydrochloride

Oral Suspension

30 mg/5 mL

antihistamine

INDOOR / OUTDOOR ALLERGY RELIEF

Dosing Cup Included

Wash and let air dry

after each use

12 HR

Berry

FLAVOR

Alcohol & Dye FREE

8 fl. oz. (240 mL)

 <p>NDC 58602-426-20</p> <p>NON-DROWSY</p> <p>Ages 2 Years & Older</p> <p>Children's</p> <p>Fexofenadine Hydrochloride</p> <p>Oral Suspension</p> <p>30 mg/5 mL</p> <p>antihistamine</p> <p>INDOOR / OUTDOOR ALLERGY RELIEF</p> <p>Dosing Cup Included Wash and let air dry after each use</p> <p>12 HR</p>  <p>Berry FLAVOR</p> <p>Alcohol & Dye FREE</p> <p>8 fl. oz. (240 mL)</p>	<p>Drug Facts</p> <p>Active ingredient (in each 5 mL) Fexofenadine Hydrochloride USP 30 mg.....Antihistamine</p> <p>Purpose Antihistamine</p> <p>Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: <ul style="list-style-type: none"> ■ runny nose ■ itchy, watery eyes ■ sneezing ■ itching of the nose or throat </p> <p>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.</p> <p>When using this product <ul style="list-style-type: none"> ■ 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) </p> <p>Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.</p> <p>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 (1-800-222-1222) right away.</p> <p>Directions <ul style="list-style-type: none"> ■ shake well before using ■ use only with enclosed dosing cup <table border="0"> <tr> <td>adults and children 12 years of age and over</td> <td>take 10 mL every 12 hours; do not take more than 20 mL in 24 hours →</td> </tr> </table> </p>	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 →	<p>Drug Facts (continued)</p> <table border="1"> <tr> <td>children 2 to under 12 years of age</td> <td>take 5 mL every 12 hours; do not take more than 10 mL in 24 hours</td> </tr> <tr> <td>children under 2 years of age</td> <td>ask a doctor</td> </tr> <tr> <td>adults 65 years of age and older</td> <td>ask a doctor</td> </tr> <tr> <td>consumers with kidney disease</td> <td>ask a doctor</td> </tr> </table> <p>Note: mL = milliliters</p> <p>Other information <ul style="list-style-type: none"> ■ each 5 mL contains: phosphorus 15 mg and sodium 18 mg ■ safety sealed: do not use if carton is opened or seal under cap opening is broken or missing ■ store between 20° to 25°C (68° to 77°F) </p> <p>Inactive ingredients art strawberry flavor, dibasic sodium phosphate anhydrous, edetate disodium, ethylparaben, methylparaben, modified food starch (corn), monobasic sodium phosphate, poloxamer 407, propylene glycol, purified water, sucrose, titanium dioxide, triacetin, xanthan gum, xylitol.</p> <p>Questions or comments? call 1-855-274-4122 (Monday – Friday 8:30 AM to 5:00 PM EST)</p> <p>Distributed by: AUROHEALTH LLC 279 Princeton-Hightstown Road East Windsor, NJ 08520</p> <p>Made in India Code: AP/DRUGS/04/2016</p> <p style="text-align: center;">P1433031</p> <p>Lot: _____ EXP.: _____</p>	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
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<p>Unvarnished Zone (dotted line not for printing)</p>												

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 8 fl. oz. (240 mL Bottle) Carton Container Label

AUROHEALTH

NDC 58602-426-20

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

Ages 2 Years & Older

Children's

Fexofenadine Hydrochloride

Oral Suspension

30 mg/5 mL

antihistamine

12 HR

NON-DROWSY

Liquid

INDOOR / OUTDOOR ALLERGY RELIEF

✓ **Sneezing**

✓ **Runny Nose**

✓ **Itchy, Watery Eyes**

✓ **Itchy Nose or Throat**

Use Only With

Enclosed Dosing Cup

Wash and let air dry after each use

Berry

FLAVOR

Alcohol & Dye FREE

8 fl. oz. (240 mL)

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	
STRAWBERRY (UNII: 4J2TY8Y81V)				
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
ETHYLPARABEN (UNII: 14255EXE39)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)				
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SUCROSE (UNII: C151H8M554)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
TRIACETIN (UNII: XHX3C3X673)				
XANTHAN GUM (UNII: TTV12P4NEE)				
XYLITOL (UNII: VCQ006KQ1E)				
Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor	BERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-426-24	1 in 1 CARTON	05/23/2023	
1		120 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:58602-426-20	1 in 1 CARTON	05/23/2023	
2		240 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA213466	05/23/2023		

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650918514	ANALYSIS(58602-426) , MANUFACTURE(58602-426)

Revised: 6/2023

Aurohealth LLC