CHILDRENS ALLERGY- fexofenadine hydrochloride suspension
H2-Pharma, LLC

Children's Allergy

Drug Facts

Active ingredient (in each 5 mL)

Fexofenadine HCl, 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:** sodium 18 mg
- store between 20° to 25°C (68° to 77°F)
- before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredients

artificial raspberry flavor, butylparaben, edetate disodium, poloxamer 407, propylene glycol, propylparaben, purified water, sodium phosphate dibasic, sodium phosphate monobasic, sucrose, titanium dioxide, xanthan gum, xylitol

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Distributed by: **H2-Pharma, LLC**
Montgomery, AL 36117

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Carton

NDC 61269-527-98

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

Children's
Allergy

Fexofenadine HCl
Oral Suspension 30 mg/5 mL

Antihistamine

Indoor/Outdoor allergy relief
Sneezing
Runny nose
Itchy, watery eyes
Itchy nose or throat

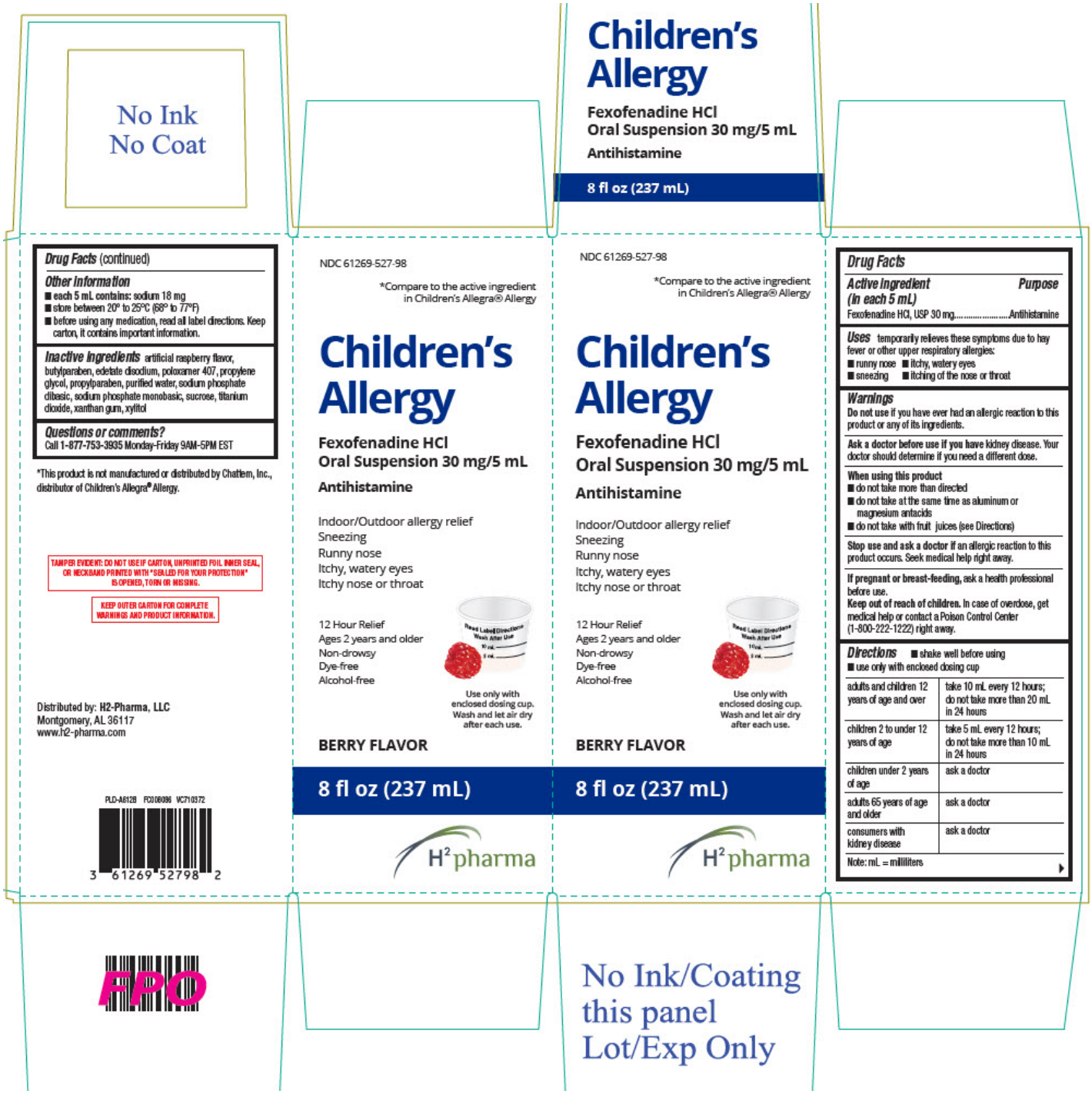
12 Hour Relief
Ages 2 years and older
Non-drowsy
Dye-free
Alcohol-free

Use only with
enclosed dosing cup.
Wash and let air dry
after each use.

BERRY FLAVOR

8 fl oz (237 mL)

H^2 pharma



CHILDRENS ALLERGY

fexofenadine hydrochloride suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61269-527
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
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
SUCROSE (UNII: C151H8M554)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XANTHAN GUM (UNII: TTV12P4NEE)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61269-527-94	1 in 1 CARTON	07/18/2022	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:61269-527-98	1 in 1 CARTON	07/18/2022	
2		237 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	ANDA203330	07/18/2022	

Labeler - H2-Pharma, LLC (028473634)

Revised: 7/2022 H2-Pharma, LLC