

CHILDRENS ALLERGY RELIEF- fexofenadine hcl tablet
PLD Acquisitions LLC DBA Avéma Pharma Solutions

DRUG FACTS

Active ingredient (in each tablet)

Fexofenadine HCL USP 30 mg

Purpose

Antihistamine

Uses

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

- runny nose
- sneezing
- itchy, watery eyes
- 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 (1-

800-222-1222).

Directions

adults and children 12 years of age and over	take two 30 mg tablets with water every 12 hours; do not take more than 4 tablets in 24 hours
children 6 to under 12 years of age	take one tablet with water every 12 hours; do not take more than 2 tablets in 24 hours
children under 6 years of age	do not use
adults 65 years of age and older	ask a doctor
consumers with kidney disease	ask a doctor

Other information

- Tamper Evident: do not use if printed safety seal under cap is broken or missing
- store between 20° and 25°C (68° and 77°F)
- protect from excessive moisture

Inactive ingredients

colloidal silicon dioxide, hypromellose, light liquid paraffin magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide, yellow iron oxide

Questions or comments?

Principal Display Panel

*Compare to the active ingredient in Children's Allegra® Allergy 12 Hour

Children's Allergy Relief

Fexofenadine HCL USP 30 mg

Antihistamine

24 Hour Relief of:

- sneezing
- runny nose
- itchy, watery eyes
- itchy nose or throat

Indoor and outdoor allergy relief

Non-drowsy

Tablets

*This product is not manufactured or distributed by Chattem Inc., distributor of Allegra® Allergy 12 hour.

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Product Label

NDC 63548-0662-5

*Compare to the active ingredient in Children's Allegra® Allergy 12 Hour

Children's Allergy Relief


Fexofenadine HCl USP 30 mg Antihistamine

12-hour relief of

- ✓ Sneezing
- ✓ Runny nose
- ✓ Itchy, watery eyes
- ✓ Itchy nose or throat

For ages 6 years and older
Indoor and outdoor allergy relief
Non-drowsy

500 Tablets




Actual Size

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Drug Facts	Purpose Antihistamine
Active ingredient (in each tablet) Fexofenadine HCl USP 30 mg	
Uses Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ 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 (1-800-222-1222). (optional)	

Distributed by:
Specific to customer's labeling guide.
Must state either: manufacturer, packer, or distributor.



PLD-A513A LB000000
Lot No.:
Exp. Date:

PEEL HERE

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Drug Facts (continued under label)

Drug Facts (continued)	
Directions	adults and children 12 years of age and over: take two 30 mg tablets with water every 12 hours; do not take more than 4 tablets in 24 hours children 6 to under 12 years of age: take one tablet with water every 12 hours; do not take more than 2 tablets in 24 hours children under 6 years of age: do not use adults 65 years of age and older: ask a doctor consumers with kidney disease: ask a doctor
Other information	■ Tamper Evident: do not use if printed safety seal under cap is broken or missing ■ store between 20° and 25°C (68° and 77°F) ■ protect from excessive moisture
Inactive ingredients	colloidal silicon dioxide; hypromellose; light liquid paraffin, magnesium stearate, microcrystalline cellulose; polyethylene glycol, polyacrylate 80, pregelatinized starch, red iron oxide, sodium starch glycolate, talc, titanium dioxide, yellow iron oxide
Questions or comments? (specific to customer's labeling guide)	Call 1-XXX-XXX-XXXX DAVIS & ZONE

CHILDRENS ALLERGY RELIEF

CHILDRENS ALLERGY RELIEF

fexofenadine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63548-0662
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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	6mm
Flavor		Imprint Code	J;42
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63548-0662-5	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204097	10/01/2019	

Revised: 2/2023

PLD Acquisitions LLC DBA Avéma Pharma Solutions