FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE- fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, extended release
PUBLIX SUPER MARKETS, INC

Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride

Drug Facts

Active ingredients (in each extended-release tablet)

Fexofenadine HCl, USP 60 mg

Pseudoephedrine HCl, USP 120 mg

Purpose

Antihistamine

Nasal Decongestant

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
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

Warnings

Do not use

- if you have ever had an allergic reaction to this product or any of its ingredients
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have difficulty swallowing

Ask a doctor before use if you have

- heart disease
- thyroid disease

- glaucoma
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- 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.
- symptoms do not improve within 7 days or are accompanied by a fever
- you get nervous, dizzy, or sleepless

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

In case of overdose, get medical help or contact a Poison Control Center right away (1800-222-1222)

Keep Out of Reach of Children.

Directions
- do not divide, crush, chew or dissolve the tablet; swallow tablet whole

adults and children 12 years of age and over	take 1 tablet with a glass of water every 12 hours on an empty stomach; do not take more than 2 tablets in 24 hours
children under 12 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
- do not use if carton is opened or if individual blister units are torn or opened
- store between 68° to 77°F (20° to 25 °C)
- USP dissolution test is pending.

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, ethyl cellulose, ferric oxide yellow, hypromellose, lactose monohydrate, magnesuim stearate, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid.

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PUBLIX SUPER MARKETS, INC.,
3300 PUBLIX CORPORATE PARKWAY
LAKELAND, FL 33811

PRINCIPAL DISPLAY PANEL - 20 Tablet Blister Pack Carton

NDC 41415-995-20

12-HOUR • NON-DROWSY

allergyreliefD

FEXOFENADINE HCl 60 mg/ANTIHISTAMINE
PSEUDOEPHEDRINE HCl 120 mg/NASAL DECONGESTANT
EXTENDED-RELEASE TABLETS, USP

ORIGINAL PRESCRIPTION STRENGTH
ALLERGY & CONGESTION

12-hour relief of:
• Nasal and sinus congestion due to colds or allergies
• Sneezing • Runny nose • Itchy, watery eyes
• Itchy throat or nose due to allergies

INDOOR AND OUTDOOR ALLERGIES

20
EXTENDED-RELEASE
TABLETS

ACTUAL SIZE

Do not use if individual blister unit is open or torn.

*Compare to the active
ingredients of Allegra-D®

GLUE - NO COATING

Drug Facts (continued)

Ask a doctor before use if you have

- heart disease
- thyroid disease
- glaucoma
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- 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.
- symptoms do not improve within 7 days or are accompanied by a fever
- you get nervous, dizzy, or sleepless

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 (1800-222-1222).

Drug Facts (continued)

Directions

- do not divide, crush, chew or dissolve the tablet; swallow tablet whole

adults and children 12 years of age and over	take 1 tablet with a glass of water every 12 hours on an empty stomach; do not take more than 2 tablets in 24 hours
children under 12 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

- do not use if carton is opened or if individual blister units are torn or opened
- store between 68° to 77°F (20° to 25°C)
- USP dissolution test is pending.

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, ethyl cellulose, ferric oxide yellow, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid.

12-HOUR • NON-DROWSY

allergyreliefD

FEXOFENADINE HCl 60 mg/ANTIHISTAMINE
PSEUDOEPHEDRINE HCl 120 mg/NASAL DECONGESTANT
EXTENDED-RELEASE TABLETS, USP

ORIGINAL PRESCRIPTION STRENGTH
ALLERGY & CONGESTION

NDC 41415-995-20

12-HOUR • NON-DROWSY
allergyreliefD

allergyrelief D

FEXOFENADINE HCl 60 mg/ANTIHISTAMINE
PSEUDOEPHEDRINE HCl 120 mg/NASAL DECONGESTANT
EXTENDED-RELEASE TABLETS, USP

ORIGINAL PRESCRIPTION STRENGTH
ALLERGY & CONGESTION

12-hour relief of:
- Nasal and sinus congestion due to colds or allergies
- Sneezing • Runny nose • Itchy, watery eyes
- Itchy throat or nose due to allergies

INDOOR AND OUTDOOR ALLERGIES

20 EXTENDED-RELEASE TABLETS

ACTUAL SIZE

Do not use if individual blister unit is open or torn.

*Compare to the active ingredients of Allegra-D®

Drug Facts

Active ingredients (in each extended-release tablet) ***Purpose***

Fexofenadine HCl, USP 60 mg.....Antihistamine
Pseudoephedrine HCl, USP 120 mg.....Nasal Decongestant

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
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- reduces swelling of nasal passages
- temporarily relieves sinus congestion and pressure

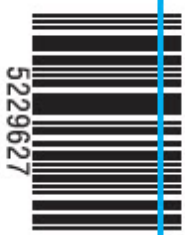
Drug Facts (continued)

- temporarily restores freer breathing through the nose

Warnings

Do not use

- if you have ever had an allergic reaction to this product or any of its ingredients
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have difficulty swallowing



12-HOUR • NON-DROWSY

allergyreliefD

FEXOFENADINE HCl 60 mg/ANTIHISTAMINE
PSEUDOEPHEDRINE HCl 120 mg/NASAL DECONGESTANT
EXTENDED-RELEASE TABLETS, USP

ORIGINAL PRESCRIPTION STRENGTH
ALLERGY & CONGESTION

Batch No.

Expiration Date:

NON VARNISH

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OR YOUR MONEY BACK

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FOR MORE
INFORMATION

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PRINCIPAL DISPLAY PANEL - 30 Tablet Blister Pack Carton

NDC 41415-995-30

12-HOUR • NON-DROWSY

allergyreliefD

FEXOFENADINE HCl 60 mg/ANTIHISTAMINE
PSEUDOEPHEDRINE HCl 120 mg/NASAL DECONGESTANT
EXTENDED-RELEASE TABLETS, USP

ORIGINAL PRESCRIPTION STRENGTH
ALLERGY & CONGESTION

12-hour relief of:
• Nasal and sinus congestion due to colds or allergies
• Sneezing • Runny nose • Itchy, watery eyes
• Itchy throat or nose due to allergies

INDOOR AND OUTDOOR ALLERGIES

30
EXTENDED-RELEASE
TABLETS

Do not use if individual blister unit is open or torn.

*Compare to the active
ingredients of Allegra-D®

GLUE - NO COATING

Drug Facts (continued)

Ask a doctor before use if you have

- heart disease
- thyroid disease
- glaucoma
- high blood pressure
- diabetes
- trouble urinating due to an enlarged prostate gland
- 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.
- symptoms do not improve within 7 days or are accompanied by a fever
- you get nervous, dizzy, or sleepless

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 (1800-222-1222).

Drug Facts (continued)

Directions

- do not divide, crush, chew or dissolve the tablet; swallow tablet whole

adults and children 12 years of age and over	take 1 tablet with a glass of water every 12 hours on an empty stomach; do not take more than 2 tablets in 24 hours
children under 12 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

- do not use if carton is opened or if individual blister units are torn or opened
- store between 68° to 77°F (20° to 25°C)
- USP dissolution test is pending.

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, dibasic calcium phosphate dihydrate, ethyl cellulose, ferric oxide yellow, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid.

12-HOUR • NON-DROWSY

allergyreliefD

FEXOFENADINE HCl 60 mg/ANTIHISTAMINE
PSEUDOEPHEDRINE HCl 120 mg/NASAL DECONGESTANT
EXTENDED-RELEASE TABLETS, USP

ORIGINAL PRESCRIPTION STRENGTH
ALLERGY & CONGESTION

NDC 41415-995-30

12-HOUR • NON-DROWSY

allergyreliefD

FEXOFENADINE HCl 60 mg/ANTIHISTAMINE
PSEUDOEPHEDRINE HCl 120 mg/NASAL DECONGESTANT
EXTENDED-RELEASE TABLETS, USP

ORIGINAL PRESCRIPTION STRENGTH
ALLERGY & CONGESTION

12-hour relief of:
- Nasal and sinus congestion due to colds or allergies
- Sneezing • Runny nose • Itchy, watery eyes
- Itchy throat or nose due to allergies

INDOOR AND OUTDOOR ALLERGIES

ACTUAL SIZE

30 EXTENDED-RELEASE TABLETS

Do not use if individual blister unit is open or torn.

*Compare to the active ingredients of Allegra-D®

Drug Facts

Active ingredients (in each extended-release tablet) — ***Purpose***

Fexofenadine HCl, USP 60 mg ..... Antihistamine
Pseudoephedrine HCl, USP 120 mg ..... Nasal Decongestant

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
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- reduces swelling of nasal passages

Drug Facts (continued)

- temporarily relieves sinus congestion and pressure
- temporarily restores freer breathing through the nose

Warnings

Do not use

- if you have ever had an allergic reaction to this product or any of its ingredients
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have difficulty swallowing

12-HOUR • NON-DROWSY

allergyreliefD

FEXOFENADINE HCl 60 mg/ANTIHISTAMINE
PSEUDOEPHEDRINE HCl 120 mg/NASAL
DECONGESTANT EXTENDED-RELEASE TABLETS, USP

ORIGINAL PRESCRIPTION STRENGTH
ALLERGY & CONGESTION

Batch No.

Expiration Date:

NON VARNISH

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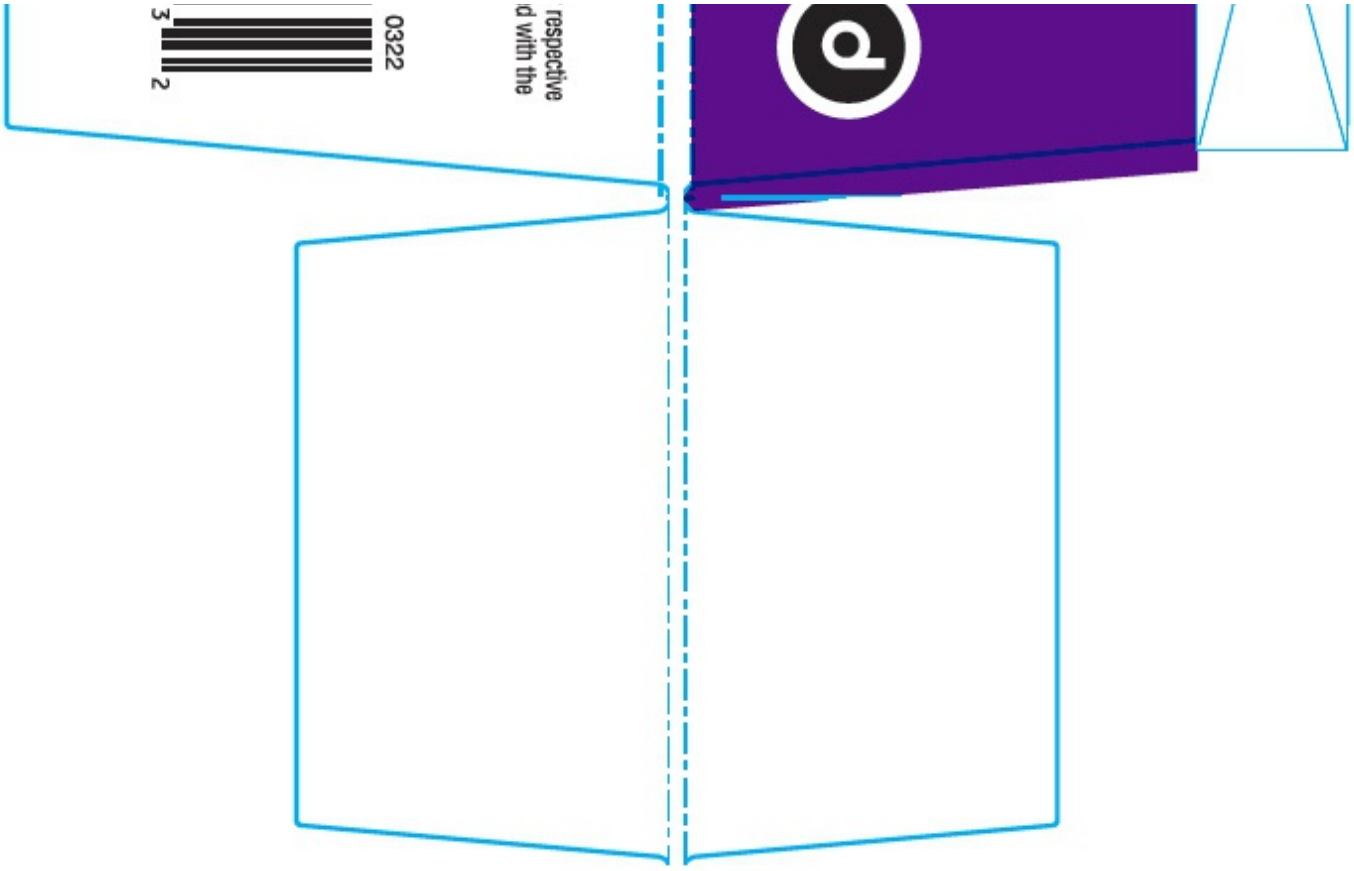

FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41415-995
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	60 mg
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	724
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41415-995-20	1 in 1 CARTON	11/08/2021	
1		20 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41415-995-30	1 in 1 CARTON	11/08/2021	
2		30 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090818	11/08/2021	

Labeler - PUBLIX SUPER MARKETS, INC (006922009)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharmaceutical Industries Limited		650445203	ANALYSIS(41415-995) , MANUFACTURE(41415-995)

Revised: 4/2022 PUBLIX SUPER MARKETS, INC