**FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE - fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, extended release**
**CVS Pharmacy**

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**Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride**

***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
- 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.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1800-222-1222).

**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 20° to 25°C (68° to 77°F)
- 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.

**Questions or comments?**

Call toll-free **1-800-818-4555 weekdays**

**Distributed by: CVS Pharmacy, Inc.**
One CVS Drive, Woonsocket, RI 02895

**PRINCIPAL DISPLAY PANEL - 30 Tablet Blister Pack Carton**

CVSHealth®
Compare to the active ingredients in Allegra-D®*
Indoor & Outdoor Allergies

NDC 69842-973-30

Original Prescription Strength
ALLERGY & CONGESTION RELIEF
Allergy Relief D
FEXOFENADINE HCl 60 mg/Antihistamine
PSEUDOEPHEDRINE HCl 120 mg/Nasal decongestant

EXTENDED RELEASE TABLETS, USP
12
HOUR

12 Hour Relief of:

- Nasal & sinus congestion due to colds or allergies
- Sneezing; Runny nose; Itchy, watery eyes & Itchy nose or throat due to allergies

DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN
Non-Drowsy
30 EXTENDED-RELEASE TABLETS
Actual Size

# Drug Facts

| Active ingredients (in each extended-release tablet) | Purpose |
|---|---|
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▶

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- if you have difficulty swallowing

▼

# Drug Facts (continued)

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

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

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# Drug Facts (continued)

## Directions

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

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## Inactive ingredients

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## Questions or comments?

Call toll-free **1-800-818-4555 weekdays**

Compare to the active ingredients in Allegra-D®*

**Indoor & Outdoor Allergies**

CVSHealth®

NDC 69842-973-30

**Original Prescription Strength**

**ALLERGY & CONGESTION RELIEF**

# Allergy Relief D

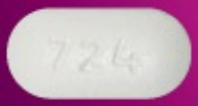
12 HOUR

**FEXOFENADINE HCl 60 mg/Antihistamine**
**PSEUDOEPHEDRINE HCl 120 mg/Nasal decongestant**
**EXTENDED RELEASE TABLETS, USP**

**12 Hour Relief of:**

- Nasal & sinus congestion due to colds or allergies
- Sneezing; Runny nose; Itchy, watery eyes & Itchy nose or throat due to allergies

DO NOT USE IF INDIVIDUAL BLISTER UNIT IS OPEN OR TORN




Actual Size

**Non-Drowsy**

**30** EXTENDED-RELEASE TABLETS

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#197233


**Distributed by: CVS Pharmacy, Inc.**
One CVS Drive, Woonsocket, RI 02895

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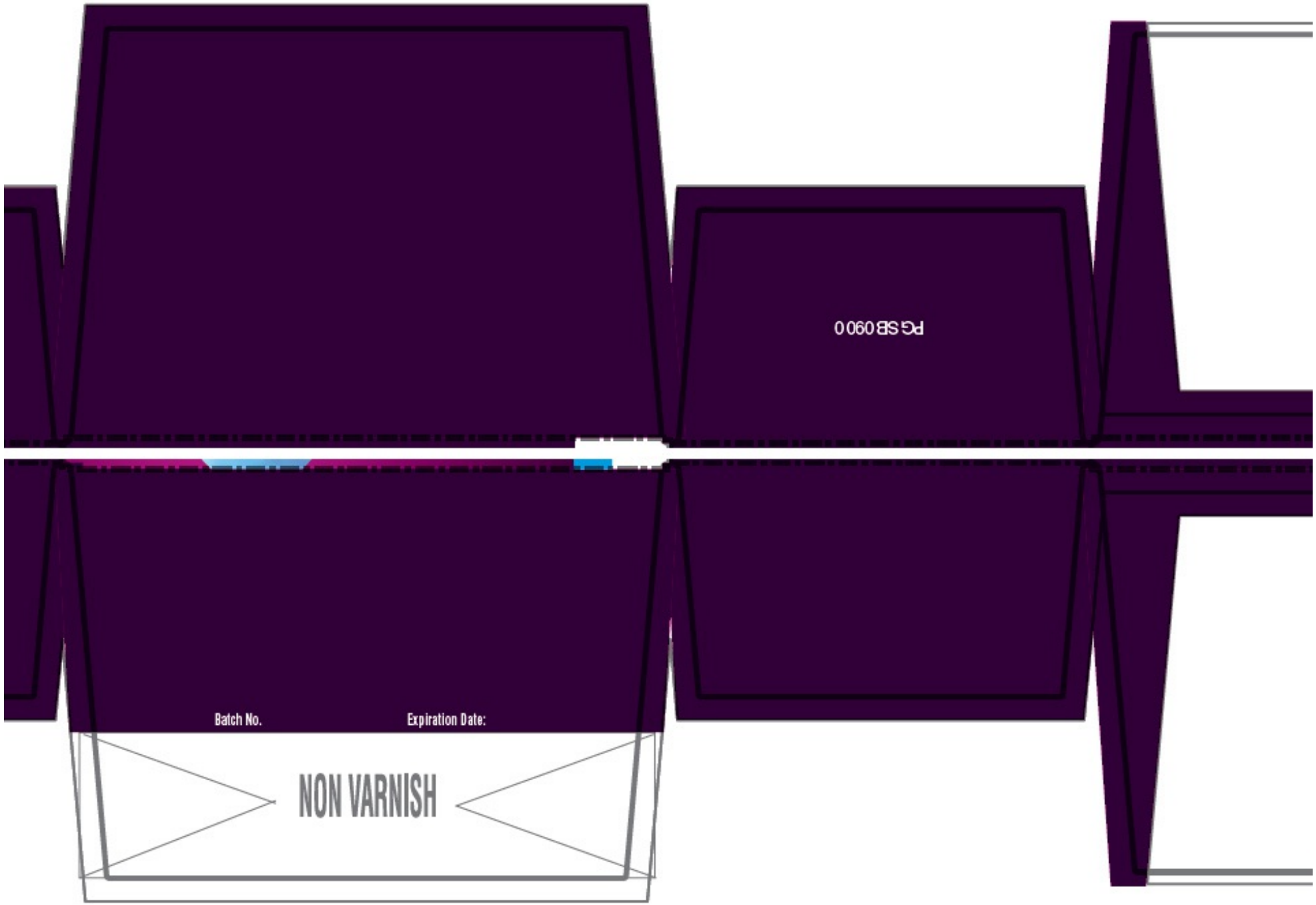
R0920



PG SB 0900
Batch No.
Expiration Date:
NON VARNISH

# FEXOFENADINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE

fexofenadine hydrochloride and pseudoephedrine hydrochloride tablet, extended release

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:69842-973 |
| **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 K30** (UNII: U725QWY32X) | |
| **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: 3WJQ0SDW1A) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | WHITE, YELLOW | **Score** | no score |
| **Shape** | OVAL (bilayer) | **Size** | 17mm |
| **Flavor** | | **Imprint Code** | 724 |
| **Contains** | | | |

**Packaging**

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:69842-973-20 | 1 in 1 CARTON | 08/27/2020 | |
| **1** | | 20 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **2** | NDC:69842-973-30 | 1 in 1 CARTON | 08/27/2020 | |
| **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 | 08/27/2020 | |

## Labeler - CVS Pharmacy (062312574)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Sun Pharmaceutical Industries Limited | | 650445203 | ANALYSIS(69842-973) , MANUFACTURE(69842-973) |

Revised: 9/2020 CVS Pharmacy