#### SIGNATURE CARE ALLERGY RELIEF D- cetirizine hydrochloride, pseudoephedrine hydrochloride tablet, film coated, extended release Safeway

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## Better Living Brands LLC Allergy Relief-D Drug Facts

## Active ingredients (in each extended release tablet)

Cetirizine HCl 5 mg

Pseudoephedrine HCl 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
- nasal congestion
- 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 or to an antihistamine containing hydroxyzine.
- 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.

# Ask a doctor before use if you have

- heart disease
- thyroid disease

- diabetes
- glaucoma
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- liver or kidney disease. Your doctor should determine if you need a different dose.

# Ask a doctor or pharmacist before use if you are

taking tranquilizers or sedatives.

## When using this product

- do not use more than directed
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

# Stop use and ask a doctor if

- an allergic reaction to this product occurs. Seek medical help right away.
- you get nervous, dizzy, or sleepless
- symptoms do not improve within 7 days or are accompanied by fever

# If pregnant or breast-feeding:

- if breast-feeding: not recommended
- if pregnant: 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

• do not break or chew tablet; swallow tablet whole

| adults and children 12 years and over  | take 1 tablet every 12 hours; do not<br>take more than 2 tablets in 24 hours. |
|--|---|
| adults 65 years and over               | ask a doctor  |
| children under 12 years of age         | ask a doctor  |
| consumers with liver or kidney disease | ask a doctor  |

### Other information

- store between 20° to 25°C (68° to 77°F)
- do not use if blister unit is broken or torn
- see side panel for lot number and expiration date
- meets USP Dissolution Test 2

#### Inactive ingredients

colloidal silicon dioxide, hypromellose, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

#### **Questions or comments?**

1-800-719-9260

### Package/Label Principal Display Panel

Compare to Zyrtec-D® active ingredients

Quality Guaranteed

**12 HOUR ALLERGY & CONGESTION** 

**ORIGINAL PRESCRIPTION STRENGTH** 

Allergy Relief-D

CETIRIZINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED RELEASE TABLETS, 5 mg/120 mg

Antihistamine/Nasal Decongestant

Indoor & Outdoor Allergies

Actual Size

12 Hour Relief of

Sneezing

Itchy, Watery Eyes

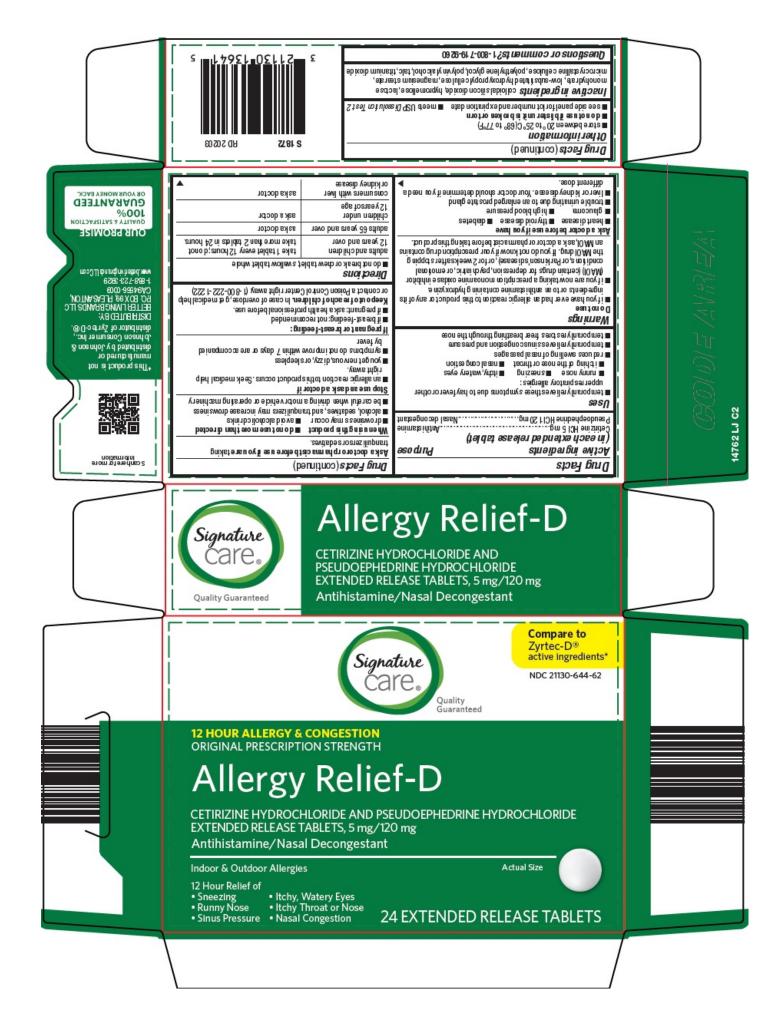
**Runny Nose** 

Itchy Throat or Nose

Sinus Pressure

**Nasal Congestion** 

24 EXTENDED RELEASE TABLETS



# SIGNATURE CARE ALLERGY RELIEF D

cetirizine hydrochloride, pseudoephedrine hydrochloride tablet, film coated, extended release

| Product Infor   |   |   |                            |                              |                               |                        |              |  |
|---|---|---|----------------------------|------------------------------|-------------------------------|------------------------|--------------|--|
|   | mation  |   |                            |                              |                               |                        |              |  |
| Product Type  |   | HUMAN OTC DE  | RUG                        | Item Code                    | Code (Source) NDC:            |                        | DC:21130-644 |  |
| Route of Administration ORAL  |   |   |                            |                              |                               |                        |              |  |
| Active Ingredient/Active Moiety   |   |   |                            |                              |                               |                        |              |  |
| Ingredient Name   |   |   |                            | <b>Basis of Strength</b>     |                               | Streng                 |              |  |
| CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE -<br>UNII:Y07261ME24)   |   |   | INE -                      | CETIRIZINE HYDROCHLORIDE     |                               | 5 mg                   |              |  |
| PSEUDOEPHEDRIN<br>(PSEUDOEPHEDRINE  |   | C <b>HLORIDE</b> (UNII: 6V<br>C9DDI9F)  | 9V2RYJ8N)                  |                              | PSEUDOEPHEDR<br>HYDROCHLORIDE |                        | 120 mg       |  |
| Inactive Ingre  | dients  |   |                            |                              |                               |                        |              |  |
| indente ingre   |   | Ingredi   | ent Nam                    | e                            |                               |                        | Strengt      |  |
| SILICON DIOXIDE   | (UNII: ETJ7Z  | -   |                            |                              |                               |                        |              |  |
|   |   | IED (UNII: 3NXW29V3   | SWO)                       |                              |                               |                        |              |  |
| LACTOSE MONOH   | YDRATE (U   | NII: EWQ57Q8I5X)  |                            |                              |                               |                        |              |  |
| LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 2165RE0K14)   |   |   |                            |                              |                               |                        |              |  |
| MAGNESIUM STEA  | ARATE (UNII   | : 70097M6I30)   |                            |                              |                               |                        |              |  |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)   |   |   |                            |                              |                               |                        |              |  |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)   |   |   |                            |                              |                               |                        |              |  |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)   |   |   |                            |                              |                               |                        |              |  |
|   |   |   |                            | 4)                           |                               |                        |              |  |
| TALC (UNII: 7SEV7J  | 4R1U)   | ECIFIED (UNII: 532E   |                            | 4)                           |                               |                        |              |  |
| TALC (UNII: 7SEV7J  | 4R1U)   | ECIFIED (UNII: 532E   |                            | A)                           |                               |                        |              |  |
| TALC (UNII: 7SEV7J  | 4R1U)   | ECIFIED (UNII: 532E   |                            | 4)                           |                               |                        |              |  |
| TALC (UNII: 7SEV7J4<br>TITANIUM DIOXID  | 4R1U)<br>E (UNII: 15F   | ecified (Unii: 532e<br>IX9V2JP)   |                            | A)                           |                               |                        |              |  |
| TALC (UNII: 7SEV7)<br>TITANIUM DIOXID<br>Product Chara  | 4R1U)<br>E (UNII: 15F   | ecified (Unii: 532e<br>IX9V2JP)   |                            | A)                           |                               | no score               |              |  |
| TALC (UNII: 7SEV7)<br>TITANIUM DIOXID<br>Product Chara<br>Color   | 4R1U)<br>E (UNII: 15F   | ECIFIED (UNII: 532E<br>IX9V2JP)<br>CS   | 359J990)                   | A)                           |                               | no score<br>10mm       |              |  |
| TALC (UNII: 7SEV7)<br>TITANIUM DIOXID<br>Product Chara<br>Color<br>Shape  | 4R1U)<br>E (UNII: 15F   | ECIFIED (UNII: 532E<br>IX9V2JP)<br>CS<br>WHITE  | Score                      |                              |                               |                        |              |  |
| TALC (UNII: 7SEV7)<br>TITANIUM DIOXID<br>Product Chara<br>Color<br>Shape<br>Flavor  | 4R1U)<br>E (UNII: 15F   | ECIFIED (UNII: 532E<br>IX9V2JP)<br>CS<br>WHITE  | Score<br>Size              |                              |                               | 10mm                   |              |  |
| TALC (UNII: 7SEV7)<br>TITANIUM DIOXID<br>Product Chara<br>Color<br>Shape<br>Flavor  | 4R1U)<br>E (UNII: 15F   | ECIFIED (UNII: 532E<br>IX9V2JP)<br>CS<br>WHITE  | Score<br>Size              |                              |                               | 10mm                   |              |  |
| TALC (UNII: 7SEV7)<br>TITANIUM DIOXID<br>Product Chara<br>Color<br>Shape<br>Flavor<br>Contains  | 4R1U)<br>E (UNII: 15F   | ECIFIED (UNII: 532E<br>IX9V2JP)<br>CS<br>WHITE  | Score<br>Size              |                              |                               | 10mm                   |              |  |
| TALC (UNII: 7SEV7)<br>TITANIUM DIOXID<br>Product Chara<br>Color<br>Shape<br>Flavor<br>Contains<br>Packaging   | 4R1U)<br>E (UNII: 15F   | ECIFIED (UNII: 532E<br>IX9V2JP)<br>CS<br>WHITE  | Score<br>Size<br>Imprint ( | Code                         | arketing Start<br>Date        | 10mm<br>L147<br>Market | ting Enc     |  |
| TALC (UNII: 7SEV7)<br>TITANIUM DIOXID<br>Product Chara<br>Color<br>Shape<br>Flavor<br>Contains<br>Packaging   | 4R1U)<br>E (UNII: 15F<br>acteristi<br>24 in 1 CA                            | ECIFIED (UNII: 532E<br>IX9V2JP)<br>CS<br>WHITE<br>ROUND<br>Package Descr                                | Score<br>Size<br>Imprint ( | Code<br>M<br>02/1            | -                             | 10mm<br>L147<br>Market | ting End     |  |
| TALC (UNII: 7SEV7)<br>TITANIUM DIOXID<br>Product Chara<br>Color<br>Shape<br>Flavor<br>Contains<br>Packaging<br># Item Code<br>1 NDC:21130-644-      | 4R1U)<br>E (UNII: 15F<br>acteristi<br>24 in 1 CA                            | ECIFIED (UNII: 532E<br>IX9V2JP)<br>CS<br>WHITE<br>ROUND<br>Package Descr                                | Score<br>Size<br>Imprint ( | Code<br>M<br>02/1            | Date                          | 10mm<br>L147<br>Market | -            |  |
| TALC (UNII: 7SEV7)<br>TITANIUM DIOXID<br>Product Chara<br>Color<br>Shape<br>Flavor<br>Contains<br>Packaging<br># Item Code<br>1 NDC:21130-644-<br>2 | 4R1U)<br>E (UNII: 15F<br>acteristi<br>24 in 1 CAI<br>1 in 1 BLIS<br>Product | ECIFIED (UNII: 532E<br>IX9V2JP)<br>CS<br>WHITE<br>ROUND<br>Package Descr<br>RTON<br>TER PACK; Type 0: N | Score<br>Size<br>Imprint ( | Code<br>M<br>02/1            | Date                          | 10mm<br>L147<br>Market | -            |  |
| TALC (UNII: 7SEV7)   TITANIUM DIOXID   Product Chara   Color   Shape   Flavor   Contains   Packaging   # Item Code   1 NDC:21130-644-<br>62         | 4R1U)<br>E (UNII: 15F<br>acteristi<br>24 in 1 CAI<br>1 in 1 BLIS<br>Product | ECIFIED (UNII: 532E<br>IX9V2JP)<br>CS<br>WHITE<br>ROUND<br>Package Descr<br>RTON<br>TER PACK; Type 0: N | Score<br>Size<br>Imprint ( | Code<br>M<br>02/1<br>ination | Date                          | 10mm<br>L147<br>Market | -            |  |

| Category | Citation   | Date       | Date |
|----------|------------|------------|------|
| ANDA     | ANDA210719 | 02/16/2021 |      |
|          |            |            |      |

# Labeler - Safeway (009137209)

Revised: 2/2021

Safeway