**SINUS RELIEF DAYTIME, NIGHTTIME- acetaminophen, diphenhydramine hcl, guaifenesin, phenylephrine hcl**
**Rite Aid Corporation**

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**Rite Aid 44-615694**

### *Active ingredients (in each caplet) (Sinus Day)*

Acetaminophen 325 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

### *Purpose*

Pain reliever
Expectorant
Nasal decongestant

### *Active ingredients (in each caplet) (Sinus Night)*

Acetaminophen 325 mg
Diphenhydramine HCl 12.5 mg
Phenylephrine HCl 5 mg

### *Purpose*

Pain reliever
Antihistamine/cough suppressant
Nasal decongestant

### *Uses*

- temporarily relieves:
  - nasal congestion
  - headache
  - minor aches and pains
  - sinus congestion and pressure
  - cough ***(Nighttime only)***
  - runny nose and sneezing ***(Nighttime only)***
- temporarily promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive ***(Daytime only)***

### *Warnings*

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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 ever had an allergic reaction to this product or any of its ingredients
- with any other product containing diphenhydramine, even one used on skin ***(Nighttime only)***

**Ask a doctor before use if you have**

- heart disease
- high blood pressure
- liver disease
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis ***(Nighttime only)***
- glaucoma ***(Nighttime only)***

**Ask a doctor or pharmacist before use if you are**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers ***(Nighttime only)***

**When using this product**

- **do not exceed recommended dosage**
- excitability may occur, especially in children ***(Nighttime only)***
- marked drowsiness may occur ***(Nighttime only)***
- alcohol, sedatives, and tranquilizers may increase drowsiness ***(Nighttime only)***
- be careful when driving a motor vehicle or operating machinery ***(Nighttime only)***

- avoid alcoholic beverages ***(Nighttime only)***

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- cough comes back or occurs with rash or headache that lasts.

These could be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**If taking NIGHTTIME and DAYTIME products, carefully read each section to ensure correct dosing. Do not take DAY & NIGHT at the same time.**

***Directions***

- **do not use more than directed**
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years and over: take 2 caplets every 4 hours
- children under 12 years: do not use

***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

***Inactive ingredients (Daytime only)***

corn starch, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

***Inactive ingredients (Nighttime only)***

corn starch, croscarmellose sodium, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, iron oxide yellow, magnesium stearate, methacrylic acid and

ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium bicarbonate, stearic acid, talc, titanium dioxide

***Questions or comments?***

**1-800-426-9391**

***Principal display panel***

NDC 11822-5694-9

Compare to the active ingredients in **Maximum Strength Mucinex® SINUS-MAX® Day & Night***

**MAXIMUM STRENGTH**

**SINUS** RELIEF

| | |
|---|---|
| **ACETAMINOPHEN** | **ACETAMINOPHEN** |
| GUAIFENESIN | DIPHENHYDRAMINE HCl |
| PHENYLEPHRINE HCl | PHENYLEPHRINE HCl |
| PAIN RELIEVER | PAIN RELIEVER |
| EXPECTORANT | ANTIHISTAMINE / COUGH SUPPRESSANT |
| NASAL DECONGESTANT | NASAL DECONGESTANT |
| DAYTIME | NIGHTTIME |
| Temporarily relieves sinus pressure, headache & congestion | Temporarily relieves nasal congestion, sinus pressure & pain |
| Thins & loosens mucus | Runny nose, sneezing & cough |
| For ages 12 & over | For ages 12 & over |
| **ACTUAL SIZE** | **ACTUAL SIZE** |
| **12** | **8** |
| **DAYTIME** | **NIGHTTIME** |
| CAPLETS | CAPLETS |

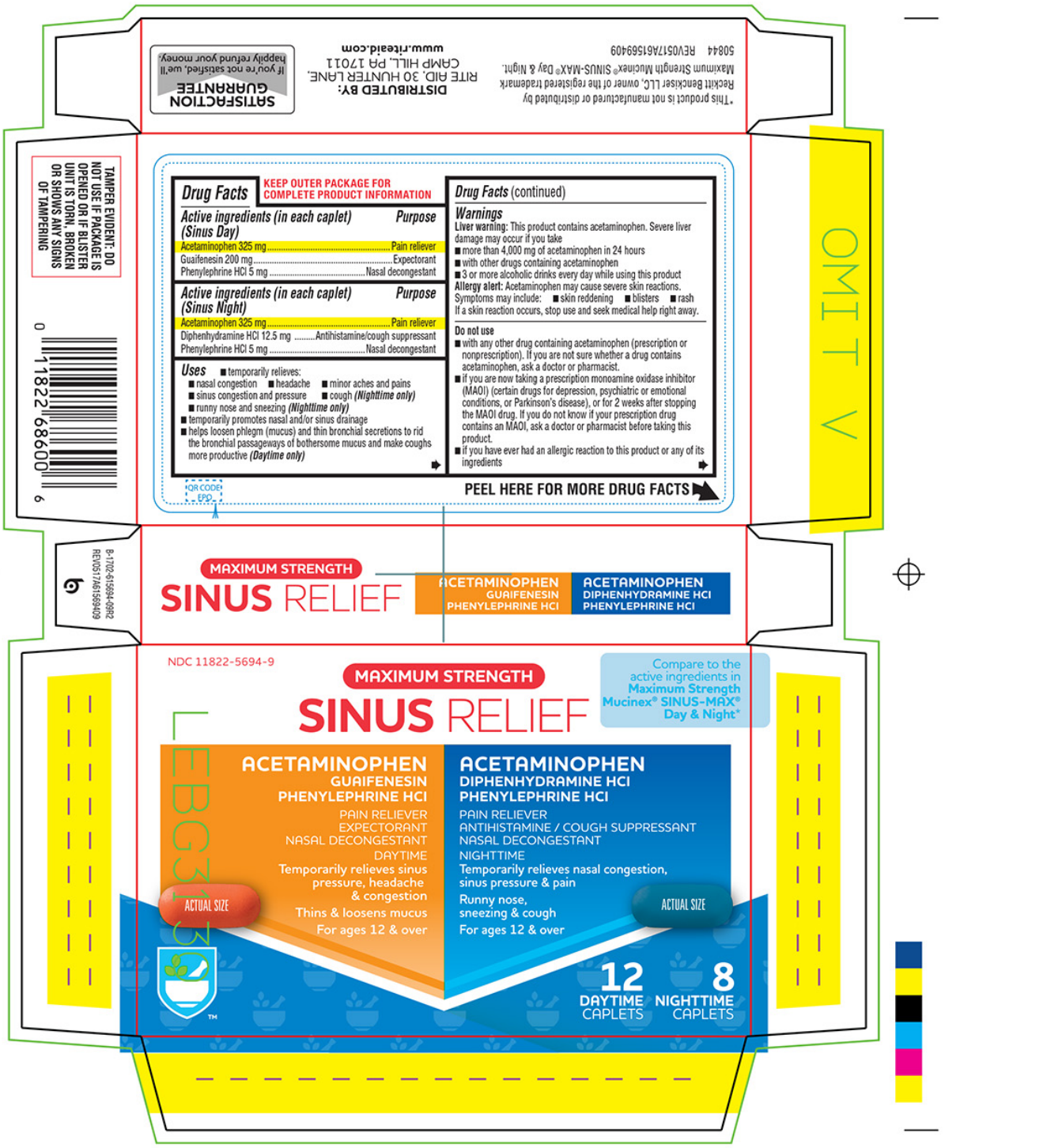
**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

**DISTRIBUTED BY:**
RITE AID, 30 HUNTER LANE,
CAMP HILL, PA 17011
**www.riteaid.com**

**SATISFACTION GUARANTEE**
If you’re not satisfied, we’ll happily refund your money.

*This product is not manufactured or distributed by Reckitt Benckiser LLC, owner of the registered trademark Maximum Strength Mucinex® SINUS-MAX® Day & Night.

50844 REV0517A61569409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50844 REV0517A61569409
DISTRIBUTED BY:
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TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING
0 11822 68600 6
B-1702-615694-09R2
REV0517A61569409
Drug Facts
KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION
Active ingredients (in each caplet) (Sinus Day) Purpose
Acetaminophen 325 mg ..... Pain reliever
Guaifenesin 200 mg ..... Expectorant
Phenylephrine HCl 5 mg ..... Nasal decongestant
Active ingredients (in each caplet) (Sinus Night) Purpose
Acetaminophen 325 mg ..... Pain reliever
Diphenhydramine HCl 12.5 mg ..... Antihistamine/cough suppressant
Phenylephrine HCl 5 mg ..... Nasal decongestant
Uses
■ temporarily relieves:
■ nasal congestion ■ headache ■ minor aches and pains
■ sinus congestion and pressure ■ cough (Nighttime only)
■ runny nose and sneezing (Nighttime only)
■ temporarily promotes nasal and/or sinus drainage
■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (Daytime only)
Drug Facts (continued)
Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
■ more than 4,000 mg of acetaminophen in 24 hours
■ with other drugs containing acetaminophen
■ 3 or more alcoholic drinks every day while using this product
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash
If a skin reaction occurs, stop use and seek medical help right away.
Do not use
■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
■ 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 ever had an allergic reaction to this product or any of its ingredients
QR CODE EPD
PEEL HERE FOR MORE DRUG FACTS
OMIT V
MAXIMUM STRENGTH
SINUS RELIEF
ACETAMINOPHEN GUAIFENESIN PHENYLEPHRINE HCl
ACETAMINOPHEN DIPHENHYDRAMINE HCl PHENYLEPHRINE HCl
NDC 11822-5694-9
MAXIMUM STRENGTH
SINUS RELIEF
Compare to the active ingredients in Maximum Strength Mucinex® SINUS-MAX® Day & Night*
EBG31G
ACETAMINOPHEN
GUAIFENESIN
PHENYLEPHRINE HCl
PAIN RELIEVER
EXPECTORANT
NASAL DECONGESTANT
DAYTIME
Temporarily relieves sinus pressure, headache & congestion
Thins & loosens mucus
For ages 12 & over
ACTUAL SIZE
ACETAMINOPHEN
DIPHENHYDRAMINE HCl
PHENYLEPHRINE HCl
PAIN RELIEVER
ANTIHISTAMINE / COUGH SUPPRESSANT
NASAL DECONGESTANT
NIGHTTIME
Temporarily relieves nasal congestion, sinus pressure & pain
Runny nose, sneezing & cough
For ages 12 & over
ACTUAL SIZE
12 DAYTIME CAPLETS
8 NIGHTTIME CAPLETS
Yellow - Magenta - Cyan - Black - No Coat - Reflex
ADHESIVE AREA
Drug Facts (continued)
■ with any other product containing diphenhydramine, even one used on skin (Nighttime only)
Ask a doctor before use if you have
■ heart disease ■ high blood pressure
■ liver disease ■ thyroid disease ■ diabetes
■ difficulty in urination due to enlargement of the prostate gland
■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
■ cough that occurs with too much phlegm (mucus)
■ a breathing problem such as emphysema or chronic bronchitis (Nighttime only)
■ glaucoma (Nighttime only)
Ask a doctor or pharmacist before use if you are
■ taking the blood thinning drug warfarin
■ taking sedatives or tranquilizers (Nighttime only)
When using this product
■ do not exceed recommended dosage
■ excitability may occur, especially in children (Nighttime only)
■ marked drowsiness may occur (Nighttime only)
■ alcohol, sedatives, and tranquilizers may increase drowsiness (Nighttime only)
Drug Facts (continued)
■ be careful when driving a motor vehicle or operating machinery (Nighttime only)
■ avoid alcoholic beverages (Nighttime only)
Stop use and ask a doctor if
■ nervousness, dizziness, or sleeplessness occur
■ pain, nasal congestion, or cough gets worse or lasts more than 7 days ■ new symptoms occur
■ fever gets worse or lasts more than 3 days
■ redness or swelling is present
■ cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.
If taking NIGHTTIME and DAYTIME products, carefully read each section to ensure correct dosing. Do not take DAY & NIGHT at the same time.
ADHESIVE AREA
ADHESIVE AREA
ADHESIVE AREA
Drug Facts (continued)
Directions
■ do not use more than directed
■ do not take more than 12 caplets in any 24-hour period
■ adults and children 12 years and over: take 2 caplets every 4 hours
■ children under 12 years: do not use
Other information
■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
■ see end flap for expiration date and lot number
Inactive ingredients (Daytime only)
corn starch, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide
Drug Facts (continued)
Inactive ingredients (Nighttime only)
corn starch, croscarmellose sodium, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, iron oxide yellow, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium bicarbonate, stearic acid, talc, titanium dioxide
Questions or comments? 1-800-426-9391
50844
REV0517B61569409
R-1702-615694-09SM-DF
ADHESIVE AREA
ADHESIVE AREA

# SINUS RELIEF DAYTIME, NIGHTTIME

acetaminophen, diphenhydramine hcl, guaifenesin, phenylephrine hcl kit

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:11822-5694 |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:11822-5694-9 | 1 in 1 CARTON; Type 0: Not a Combination Product | 06/16/2017 | |

| Quantity of Parts | | |
|---|---|---|
| **Part #** | **Package Quantity** | **Total Product Quantity** |
| **Part 1** | 1 BLISTER PACK | 12 |
| **Part 2** | 1 BLISTER PACK | 8 |

## Part 1 of 2

## SINUS RELIEF DAYTIME

acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated

| Product Information | |
|---|---|
| **Route of Administration** | ORAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| **GUAIFENESIN** (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ) | GUAIFENESIN | 200 mg |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **CROSPOVIDONE, UNSPECIFIED** (UNII: 2S7830E561) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |

| | |
|---|---|
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MALTODEXTRIN** (UNII: 7CVR7L4A2D) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POLYVINYL ALCOHOL, UNSPECIFIED** (UNII: 532B59J990) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | orange | **Score** | no score |
| **Shape** | OVAL | **Size** | 19mm |
| **Flavor** | | **Imprint Code** | 44;615 |
| **Contains** | | | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 12 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 |
|---|---|---|---|
| OTC Monograph Drug | M012 | 06/16/2017 | |

## Part 2 of 2

## SINUS RELIEF NIGHTTIME

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated

### Product Information

| | |
|---|---|
| **Route of Administration** | ORAL |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| **DIPHENHYDRAMINE HYDROCHLORIDE** (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 12.5 mg |

| | | |
|---|---|---|
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **CROSPOVIDONE, UNSPECIFIED** (UNII: 2S7830E561) | |
| **FD&C BLUE NO. 1 ALUMINUM LAKE** (UNII: J9EQA3S2JM) | |
| **FD&C BLUE NO. 2--ALUMINUM LAKE** (UNII: 4AQJ3LG584) | |
| **FERRIC OXIDE YELLOW** (UNII: EX438O2MRT) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER** (UNII: NX76LV5T8J) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POLYVINYL ALCOHOL, UNSPECIFIED** (UNII: 532B59J990) | |
| **POVIDONE, UNSPECIFIED** (UNII: FZ989GH94E) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SODIUM BICARBONATE** (UNII: 8MDF5V39QO) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | blue | **Score** | no score |
| **Shape** | OVAL | **Size** | 19mm |
| **Flavor** | | **Imprint Code** | 44;694 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 8 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 |
|---|---|---|---|
| OTC Monograph Drug | M012 | 06/16/2017 | |


## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M012 | 06/16/2017 | |

## Labeler - Rite Aid Corporation (014578892)

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 038154464 | pack(11822-5694) |

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867837 | manufacture(11822-5694) , pack(11822-5694) |

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867894 | manufacture(11822-5694) |

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 967626305 | pack(11822-5694) |

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 117025878 | manufacture(11822-5694) |

Revised: 3/2024 Rite Aid Corporation