

**SINUS RELIEF DAYTIME NIGHTTIME- acetaminophen, diphenhydramine hcl,
guaifenesin, phenylephrine hcl
Kroger Company**

Kroger 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 (1-800-222-1222) 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

COMPARE TO the active ingredients of MAXIMUM STRENGTH MUCINEX® SINUSMAX® DAY & NIGHT

*See bottom panel

NDC 30142-616-09

OUR PHARMACIST RECOMMENDED

Maximum Strength

FOR AGES 12+

Kroger®

Sinus Relief

| | |
|---|-------------------------------------|
| DAYTIME | NIGHTTIME |
| Acetaminophen / Pain Reliever | Acetaminophen /Pain Reliever |
| Guafenesin / Expectorant | Diphenhydramine HCl / |
| Phenylephrine HCl / Nasal Decongestant | Antihistamine/Cough Suppressant |
| | Phenylephrine HCl / |
| | Nasal Decongestant |
| RELIEVES: | RELIEVES: |
| Sinus Pressure | Nasal Congestion |
| Headache | Sinus Pressure & Pain |
| & Congestion | Runny Nose |
| Thins & Loosens Mucus | Sneezing & Cough |
| actual size | actual size |
| 12 CAPLETS | 8 CAPLETS |

*Maximum Strength Mucinex® SINUS-MAX® Day & Night is a registered trademark of Reckitt Benckiser LLC, Slough, United Kingdom. Reckitt Benckiser is not aliated with The Kroger Co. or these products.

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www.kroger.com

SINUS RELIEF DAYTIME NIGHTTIME

acetaminophen, diphenhydramine hcl, guaifenesin, phenylephrine hcl kit

Product Information

| | | | |
|---------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:30142-616 |
|---------------------|----------------|---------------------------|---------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:30142-616-09 | 1 in 1 CARTON; Type 0: Not a Combination Product | 06/01/2021 | |

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

| | |
|---------------------------|---------------|
| Item Code (Source) | NDC:30142-972 |
|---------------------------|---------------|

| | |
|--------------------------------|------|
| 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) | |
| CROSPROVIDONE (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: 3WJQ0SDW1A) | |
| 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 | 06/01/2021 | |

Part 2 of 2

SINUS RELIEF NIGHTTIME

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated

Product Information

| | |
|--------------------------------|---------------|
| Item Code (Source) | NDC:30142-986 |
| 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) | |
| CROSPVIDONE (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: 3WJQ0SDW1A) | |
| 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 | 06/01/2021 | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
| | | | |

| Category | Citation | Date | Date |
|--------------------|----------|------------|------|
| OTC Monograph Drug | M012 | 06/01/2021 | |

Labeler - Kroger Company (006999528)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 038154464 | pack(30142-616) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|--|
| LNK International, Inc. | | 832867837 | manufacture(30142-616) , pack(30142-616) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 832867894 | manufacture(30142-616) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 967626305 | pack(30142-616) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 117025878 | manufacture(30142-616) |

Revised: 7/2024

Kroger Company