

DAY AND NIGHT SINUS- acetaminophen, diphenhydramine hcl, guaifenesin, phenylephrine hcl
Wal-Mart Stores Inc

Equate 44-615694

Active ingredients (in each caplet) (daytime)

Acetaminophen 325 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever

Expectorant

Nasal decongestant

Active ingredients (in each caplet) (nighttime)

Acetaminophen 325 mg

Diphenhydramine HCl 12.5 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever

Antihistamine/cough suppressant

Nasal decongestant

Uses

- temporarily relieves these common cold symptoms:
 - 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.
- with any other product containing diphenhydramine, even one used on skin **(nighttime only)**

Ask a doctor before use if you have

- heart disease
- diabetes
- liver disease
- thyroid disease
- high blood pressure
- 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)**
- avoid alcoholic beverages **(nighttime only)**
- use caution when driving a motor vehicle or operating machinery **(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
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- 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 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.

Do not take DAYTIME and NIGHTTIME products at the same time.***Directions***

- **do not take 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

- **each caplet contains:** sodium 3 mg (***daytime only***)
- **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?

1-888-287-1915

Principal Display Panel

equate™

NDC 49035-356-09

Maximum Strength

Day & Night Sinus

Day

Acetaminophen - Pain Reliever,
Guaifenesin - Expectorant,
Phenylephrine HCl / Nasal Decongestant

- Relieves sinus pressure, headache & congestion
- Thins & loosens mucus

Actual Size

10

**DAYTIME
CAPLETS**

Night

Acetaminophen - Pain Reliever,
Diphenhydramine HCl - Antihistamine/Cough Suppressant

Phenylephrine HCl / Nasal Decongestant

- Relieves nasal congestion, sinus pressure & pain
- Runny nose, sneezing & cough

Actual Size

10

**NIGHTTIME
CAPLETS**

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

Do not take **Daytime** and **Nighttime**
products at the same time.

**DISTRIBUTED BY: Walmart Inc.,
Bentonville, AR 72716**

50844 REV0824B61569409



Equate 44-615694-09

DAY AND NIGHT SINUS

acetaminophen, diphenhydramine hcl, guaifenesin, phenylephrine hcl kit

| Product Information | | | |
|---------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49035-356 |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:49035-356-09 | 1 in 1 CARTON; Type 0: Not a Combination Product | 10/23/2020 | |

Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|--------|------------------|------------------------|
| Part 1 | 1 BLISTER PACK | 10 |
| Part 2 | 1 BLISTER PACK | 10 |

Part 1 of 2

DAY SINUS

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) | |
| CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561) | |
| FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T) | |
| FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q) | |
| 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 | | 10 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 | 10/23/2020 | |

Part 2 of 2

NIGHT SINUS

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) | |
| CROSPVIDONE, 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: 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 | | 10 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 | 10/23/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012 | 10/23/2020 | |

Labeler - Wal-Mart Stores Inc (051957769)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

| | | | |
|-------------------------|--|-----------|-----------------|
| LNK International, Inc. | | 038154464 | pack(49035-356) |
|-------------------------|--|-----------|-----------------|

| Establishment | | | |
|-------------------------|---------|-----------|--|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 832867837 | manufacture(49035-356) , pack(49035-356) |

| Establishment | | | |
|-------------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 832867894 | manufacture(49035-356) |

| Establishment | | | |
|-------------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 967626305 | pack(49035-356) |

| Establishment | | | |
|-------------------------|---------|-----------|------------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 117025878 | manufacture(49035-356) |