

**SINUS PE CONGESTION DAYTIME NIGHTTIME- diphenhydramine hcl,
phenylephrine hcl
Meijer Distribution, Inc.**

Meijer 44-453485

Active ingredient (in each tablet) (Sinus Day)

Phenylephrine HCl 10 mg

Purpose

Nasal decongestant

Active ingredients (in each tablet) (Sinus Night)

Diphenhydramine HCl 25 mg

Phenylephrine HCl 10 mg

Purpose

Antihistamine

Nasal decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - nasal congestion
 - sneezing ***(Nighttime only)***
 - runny nose ***(Nighttime only)***
 - itchy, watery eyes ***(Nighttime only)***
 - itching of the nose or throat ***(Nighttime only)***
- temporarily relieves these symptoms due to the common cold:
 - nasal congestion
 - sneezing ***(Nighttime only)***
 - runny nose ***(Nighttime only)***
- temporarily relieves sinus congestion and pressure

Warnings

Do not use

- 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
- thyroid disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- 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 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

- symptoms do not improve within 7 days or occur with fever
- nervousness, dizziness, or sleeplessness occur

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.

Read each section carefully. Do not take DAYTIME and NIGHTTIME products at the same time.

Directions

- adults and children 12 years and over
 - take 1 tablet every 4 hours
 - do not take more than 6 tablets in 24 hours
- children under 12 years: do not use

Other information

- **each tablet contains:** calcium 25 mg **(Nighttime 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)

croscarmellose sodium, dextrose monohydrate, dibasic calcium phosphate dihydrate, FD&C red #40, lecithin, magnesium stearate, maltodextrin, microcrystalline cellulose, silicon dioxide, sodium carboxymethylcellulose, sodium citrate dihydrate, titanium dioxide

Inactive ingredients (Nighttime only)

croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, silicon dioxide, stearic acid, titanium dioxide, triacetin

Questions or comments?

1-800-426-9391

Principal display panel

meijer®

COMBO PACK

20 TABLETS TOTAL

NDC 79481-4534-1

| | |
|--|---|
| <p>COMPARE TO DAYTIME SUDAFED PE® SINUS CONGESTION ACTIVE INGREDIENT* NON-DROWSY Daytime Sinus PE Congestion PHENYLEPHRINE HCl 10 mg NASAL DECONGESTANT Pseudoephedrine Free Relieves Nasal Congestion 12 Tablets actual size</p> | <p>COMPARE TO NIGHTTIME SUDAFED PE® SINUS CONGESTION ACTIVE INGREDIENTS* Nighttime Sinus PE Congestion DIPHENHYDRAMINE HCl 25 mg PHENYLEPHRINE HCl 10 mg Antihistamine Nasal Decongestant Pseudoephedrine Free Relieves Nasal Congestion, Runny Nose 8 Tablets actual size</p> |
|--|---|

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 the Daytime and Nighttime
tablets at the same time.**

*This product is not manufactured
or distributed by Kenvue Inc., owner
of the registered trademark Sudafed
PE® Sinus Congestion Daytime
and Nighttime.

50844 ORG082045348509

**DIST. BY MEIJER
DISTRIBUTION, INC.
GRAND RAPIDS, MI 49544
www.meijer.com**



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Drug Facts **KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION**

Active ingredient (in each tablet) **Purpose**
(Sinus Day)
Phenylephrine HCl 10 mg Nasal decongestant

Active ingredients (in each tablet) **Purpose**
(Sinus Night)
Diphenhydramine HCl 25 mg Antihistamine
Phenylephrine HCl 10 mg Nasal decongestant

Uses
temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
nasal congestion sneezing (Nighttime only)
runny nose (Nighttime only)
itchy, watery eyes (Nighttime only)
itching of the nose or throat (Nighttime only)
temporarily relieves these symptoms due to the common cold:
nasal congestion sneezing (Nighttime only)
runny nose (Nighttime only)
temporarily relieves sinus congestion and pressure

Drug Facts (continued)

Warnings
Do not use
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
thyroid disease
high blood pressure
difficulty in urination due to enlargement of the prostate gland
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 sedatives or tranquilizers. (Nighttime only)

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

No print area
Lot no/Exp date

PEEL HERE FOR MORE DRUG FACTS



NON-DROWSY
Daytime Sinus PE Congestion

Nighttime Sinus PE Congestion



COMBO PACK
20 TABLETS TOTAL

NON-DROWSY
Daytime Sinus PE Congestion

Nighttime Sinus PE Congestion

PHENYLEPHRINE HCl 10 mg
Nasal Decongestant
Pseudoephedrine Free
Relieves Nasal Congestion
actual size
12 Tablets

DIPHENHYDRAMINE HCl 25 mg
PHENYLEPHRINE HCl 10 mg
Antihistamine
Nasal Decongestant
Pseudoephedrine Free
Relieves Nasal Congestion, Runny Nose
actual size
8 Tablets

BOTTOM (INNER)

Drug Facts (continued)
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
symptoms do not improve within 7 days or occur with fever
nervousness, dizziness, or sleeplessness occur
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.
Read each section carefully. Do not take DAYTIME and NIGHTTIME products at the same time.

Drug Facts (continued)
Directions
adults and children 12 years and over
take 1 tablet every 4 hours
do not take more than 6 tablets in 24 hours
children under 12 years: do not use
Other information
each tablet contains: calcium 25 mg (Nighttime 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)
croscarmellose sodium, dextrose monohydrate, dibasic calcium phosphate dihydrate, FD&C red #40, lecithin, magnesium stearate, maltodextrin, microcrystalline cellulose, silicon dioxide, sodium carboxymethylcellulose, sodium citrate dihydrate, titanium dioxide

Drug Facts (continued)
Inactive ingredients (Nighttime only)
croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, silicon dioxide, stearic acid, titanium dioxide, triacetin
Questions or comments? 1-800-426-9391

*This product is not manufactured or distributed by Kenvue Inc., owner of the registered trademark Sudafed[®] PE[®] Sinus Congestion Daytime and Nighttime.

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www.meijer.com



ITEM 5229167-024-001
50844
ORG082045348509
R-1214-453485-09DF

Do not take the Daytime and Nighttime tablets at the same time.

meijer 44-453485

SINUS PE CONGESTION DAYTIME NIGHTTIME

diphenhydramine hcl, phenylephrine hcl kit

Product Information

| | | | |
|---------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:79481-4534 |
|---------------------|----------------|---------------------------|----------------|

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:79481-4534-1 | 1 in 1 CARTON; Type 0: Not a Combination Product | 07/05/2023 | |

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 PE CONGESTION DAYTIME

phenylephrine hcl tablet, film coated

Product Information

| | |
|---------------------------|----------------|
| Item Code (Source) | NDC:79481-7453 |
|---------------------------|----------------|

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

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------|----------|
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| DEXTROSE MONOHYDRATE (UNII: LX22YL083G) | |
| DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |

CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)

TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | red | Score | no score |
| Shape | ROUND | Size | 7mm |
| Flavor | | Imprint Code | 44;453 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:79481-7453-2 | 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 | 07/05/2023 | |

Part 2 of 2

SINUS PE CONGESTION NIGHTTIME

diphenhydramine hcl, phenylephrine hcl tablet, film coated

Product Information

| | |
|-------------------------|----------------|
| Item Code (Source) | NDC:79481-7485 |
| Route of Administration | ORAL |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|----------------------------------|----------|
| DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M) | DIPHENHYDRAMINE HYDROCHLORIDE | 25 mg |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP) | |

| | |
|---|--|
| FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYDEXTROSE (UNII: VH2XOU12IE) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIACETIN (UNII: XHX3C3X673) | |

Product Characteristics

| | | | |
|-----------------|------|---------------------|----------|
| Color | blue | Score | no score |
| Shape | OVAL | Size | 11mm |
| Flavor | | Imprint Code | 44;485 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:79481-7485-3 | 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 | 07/05/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012 | 07/05/2023 | |

Labeler - Meijer Distribution, Inc. (006959555)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|--|
| LNK International, Inc. | | 832867837 | manufacture(79481-4534) , pack(79481-4534) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|-------------------------|
| LNK International, Inc. | | 832867894 | manufacture(79481-4534) |

| Establishment | | | |
|-------------------------|----------------|---------------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 868734088 | manufacture(79481-4534) |

| Establishment | | | |
|-------------------------|----------------|---------------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| LNK International, Inc. | | 117025878 | manufacture(79481-4534) |

Revised: 7/2024

Meijer Distribution, Inc.