

NASAL DECONGESTANT NON-DROWSY- pseudoephedrine hcl tablet, film coated
CVS Pharmacy

CVS 44-112

Active ingredient (in each tablet)

Pseudoephedrine HCl 30 mg

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- 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.

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

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor if

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

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 (1-800-222-1222) right away.

Directions

| | |
|---------------------------------------|--|
| adults and children 12 years and over | take 2 tablets every 4 to 6 hours; do not take more than 8 tablets in 24 hours |
| children ages 6 to 11 years | take 1 tablet every 4 to 6 hours; do not take more than 4 tablets in 24 hours |
| children under 6 years | do not use |

Other information

- **each tablet contains:** calcium 15 mg
- **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

croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, silicon dioxide, titanium dioxide, triacetin

Questions or comments?

1-800-426-9391

Principal Display Panel

♥CVSHealth™

Compare to the active ingredient
in Sudafed® Sinus Congestion*

Non-Drowsy

Nasal Decongestant

PSEUDOEPHEDRINE HYDROCHLORIDE

Nasal decongestant

MAXIMUM STRENGTH

Relieves:

- Nasal & sinus congestion
- Sinus pressure

24 TABLETS 30 mg EACH

Actual Size

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

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Sudafed® Sinus Congestion.
50844 REV0619A11208

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Non-Drowsy
Nasal Decongestant
PSEUDOEPHEDRINE HYDROCHLORIDE/Nasal decongestant



Drug Facts (continued)

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| | |
|-----------------------------|--|
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Questions or comments? 1-800-426-9391

Drug Facts

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Active ingredient (in each tablet) Pseudoephedrine HCl 30 mg.....Nasal decongestant

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#477074

0 50428 37833 5

No Print / No Varnish Area
Lot no. & Exp. Date

B-0231-112-08-HHR
REV0619A11208

Non-Drowsy
Nasal Decongestant
PSEUDOEPHEDRINE HYDROCHLORIDE/Nasal decongestant



Compare to the active ingredient in Sudafed® Sinus Congestion*

Non-Drowsy
Nasal Decongestant

PSEUDOEPHEDRINE HYDROCHLORIDE
Nasal decongestant

MAXIMUM STRENGTH

- Relieves:**
- Nasal & sinus congestion
 - Sinus pressure

24 TABLETS 30 mg EACH



CVS 44-112

NASAL DECONGESTANT NON-DROWSY
pseudoephedrine hcl tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59779-112 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------------|-----------------|
| PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F) | PSEUDOEPHEDRINE HYDROCHLORIDE | 30 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | |
| DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYDEXTROSE (UNII: VH2XOU12IE) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRACETIN (UNII: XHX3C3X673) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | red | Score | no score |
| Shape | ROUND | Size | 7mm |
| Flavor | | Imprint Code | 44;112 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:59779-112-08 | 1 in 1 CARTON | 08/25/1981 | |
| 1 | | 24 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:59779-112-22 | 2 in 1 CARTON | 08/25/1981 | |
| 2 | | 24 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 3 | NDC:59779-112-46 | 4 in 1 CARTON | 08/25/1981 | |
| 3 | | 24 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 | 08/25/1981 | |

Labeler - CVS Pharmacy (062312574)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 038154464 | pack(59779-112) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 832867837 | pack(59779-112) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 832867894 | manufacture(59779-112) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 868734088 | pack(59779-112) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. | | 967626305 | pack(59779-112) |

Revised: 12/2023

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