**NASAL DECONGESTANT MAXIMUM STRENGTH- pseudoephedrine hcl tablet, film coated**
**Chain Drug Consortium**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Premier Value 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**

- diabetes
- heart disease
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland

**When using this product**

**do not exceed recommended dose.**

**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 right away.

***Directions***

| | |
|---|---|
| adults and children 12 years and old | take 2 tablets every 4 to 6 hours; do not take more than 8 tablets in 24 hours |
| children ages 6 to 12 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 this product in children under 6 years of age |

***Other information***

- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- see end flap for expiration date and lot number

***Inactive ingredients***

croscarmellose sodium, dicalcium phosphate, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, silica gel, titanium dioxide, triacetin

**Questions or comments?**

**1-800-426-9391**

**Principal Display Panel**

**Premier Value®**

**NDC 68016-473-24**

***COMPARE TO THE ACTIVE INGREDIENT IN SUDAFED® CONGESTION**

*Maximum Strength*
***Nasal Decongestant***

Pseudoephedrine HCl 30 mg

Non-Drowsy

• Nasal & Sinus Congestion
• Sinus Pressure

**24 Tablets**

***PV***
INDEPENDENTLY TESTED
SATISFACTION GUARANTEED

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

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Sudafed® Congestion. 50844 ORG071211208

DISTRIBUTED BY
CHAIN DRUG CONSORTIUM
3301 NW BOCA RATON BLVD
SUITE 101, BOCA RATON, FL 33431

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

**Premier Value 44-112**

# NASAL DECONGESTANT MAXIMUM STRENGTH

pseudoephedrine hcl tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:68016-473 |
| **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) | |
| **ANHYDROUS DIBASIC CALCIUM PHOSPHATE** (UNII: L11K75P92J) | |
| **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) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **TRIACETIN** (UNII: XHX3C3X673) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |

| 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:68016-473-24 | 1 in 1 CARTON | 08/25/1981 | |
| **1** | | 24 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **2** | NDC:68016-473-96 | 4 in 1 CARTON | 08/25/1981 | |
| **2** | | 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 FINAL | part341 | 08/25/1981 | |

## Labeler - Chain Drug Consortium (101668460)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 038154464 | PACK(68016-473) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867894 | MANUFACTURE(68016-473) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 967626305 | PACK(68016-473) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 832867837 | PACK(68016-473) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| LNK International, Inc. | | 868734088 | PACK(68016-473) |

Revised: 5/2020 Chain Drug Consortium