**PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hcl tablet, film coated**
**Padagis Israel Pharmaceuticals Ltd**

*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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**Perrigo Pseudoephedrine Hydrochloride 30 mg Drug Facts**

**Active ingredient (in each tablet)**

Pseudoephedrine HCl 30 mg

**Purpose**

Nasal decongestant

**Uses**

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

**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
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged 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 a 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. (1-800-222-1222)

**Directions**

| | |
|---|---|
| adults and children 12 years and over | • take 2 tablets every 4 to 6 hours<br>• do not take more than 8 tablets in 24 hours |
| children ages 6 to 11 years | • take 1 tablet every 4 to 6 hours<br>• 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**

- **each tablet contains:** calcium 20 mg
- store at 20°-25°C (68°-77°F)
- do not use if blister unit is broken or torn

**Inactive ingredients**

carnauba wax, dibasic calcium phosphate dihydrate, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, silicon dioxide, titanium dioxide

**Questions or comments?**

**1-800-719-9260**

**Principal Display Panel**

Compare to Sudafed® Congestion active ingredient

Pseudoephedrine Hydrochloride

30 mg

Nasal Decongestant

Maximum Strength – Non-Drowsy

Sinus Pressure – Congestion

24 TABLETS, 30 mg EACH

Pseudoephedrine HCl – Sinus

actual size

Congestion

NDC 45802-432-62

**Pseudoephedrine Hydrochloride 30 mg**

Perrigo®

Compare to Sudafed® Congestion active ingredient

NDC 45802-432-62

# Pseudoephedrine Hydrochloride

## 30 mg

**Nasal Decongestant**

**Maximum Strength • Non-Drowsy**

Sinus Pressure • Congestion

24 TABLETS, 30 mg EACH

Pseudoephedrine HCl • Sinus

actual size

**Congestion**

OPEN OTHER END

Important: Read all product information before using. Keep this box for important information.

## Drug Facts

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Pseudoephedrine HCl 30 mg ..... Nasal decongestant

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## Drug Facts (continued)

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### Questions or comments?

1-800-719-9260

Distributed By

Perrigo® Allegan, MI 49010 • www.perrigo.com

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

Convenient Reclosing Tab

FSA If your doctor writes a prescription for this product, it may be covered by


# PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hcl tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:45802-432 |
| **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** |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **DIBASIC CALCIUM PHOSPHATE DIHYDRATE** (UNII: O7TSZ97GEP) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | RED | **Score** | no score |
| **Shape** | ROUND (convex) | **Size** | 7mm |
| **Flavor** | | **Imprint Code** | L432 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:45802-432-62 | 24 in 1 CARTON | 10/17/2008 | |
| **1** | | 1 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 | 10/17/2008 | |

## Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 11/2021

Padagis Israel Pharmaceuticals Ltd