

PSEUDOEPHEDRINE HYDROCHLORIDE- pseudoephedrine hcl tablet, film coated

Padagis Israel Pharmaceuticals Ltd

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	<ul style="list-style-type: none">• take 2 tablets every 4 to 6 hours• do not take more than 8 tablets in 24 hours
children ages 6 to 11 years	<ul style="list-style-type: none">• 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

- **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

- SINUS PRESSURE
- SINUS CONGESTION

24 TABLETS

actual size

NON-DROWSY

Padagis™



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

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Drug Facts (continued)

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- | | |
|---------------------------------------|----------------------------------------------------------|
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Distributed By



Allegan, MI 49010
www.padagis.com

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN
Convenient Reclosing Tab

49262 RT CS

OPEN OTHER END



OTC via **Rx**

If a prescription is written for this product it may be covered by your health plan.



3 45802-432-62 9

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: 3WJQ0SDW1A)	

POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)	

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 Drug	M012	10/17/2008	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 8/2024

Padagis Israel Pharmaceuticals Ltd