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.

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 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 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

Nasal Decongestant

Maximum Strength • Non-Drowsy

Sinus Pressure • Congestion

24 TABLETS, 30 mg EACH

Pseudoephedrine HCl • Sinus



NOT USE IF BLISTER UNIT IS BROKEN OR TORN

Tab

Convenient Reclosing



292E h 콕

> OPEN OTHER END

Important: Rea dial product information before using . Keep this box for important information .

Drug Facts

Active ingredient (in each tablet) Purpose

■ temporarily relieves sinus congestion and pressure

 temporarily relieves nasal congestion due to the common cold, hay fe ver or other upper respiratory all ergies

Warnings 9 8 1

Do not use if you are now taking a prescription mon camine oxidase inhibitor (MAOI) (certa in drugs for depression, p sychiatric, 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.

Aska doctor before use if vou have

- heart disea se high blood pressure thyroid disease diabetes
- trouble uninating due to an enlarged prostate gland

When using this product do not exceed recommended dosage

Stop use and a ska do ctor if

- nervousness, dizzines s, or sleeplessness occur
- symptom s do n ot improve within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional

Keep out of reach of children. In case of overdose, get medical help or contacta Poison Control Center rightaway 1-800-222-1222).

Drug Facts (continued)

Directions				
adults and children 12 years and o ver	■ ta ke 2 tablets every 4 to 6 hours ■ do not take more than 8 tablets in 24 hours			
children a ges 6 to 11 years	 ta ke 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 o fage			

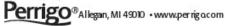
Other Information

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

Inactive Ingredients carnaubawax, dibasic calcium phosphate dihydrate, FD &C red no. 40 aluminum lake, hy promello se, m agne si um ste arate, microcrystal line cel lul ose, polyethylene glycol, polysorbate 80, silicon dioxide,

Questions or comments? 1-80 0-719-9260

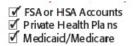
Distributed By







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





PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hcl tablet, film coated

Product	Intorm	ation
FIUGULL		ativii

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: 3MJQ0SDW1A)

POLYSORBATE 80 (UNII: 60ZP39ZG8H)

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

				-	
	•		\sim	ш	a
а	ĸ	а	u		

#	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