

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

Perrigo Pseudoephedrine Hydrochloride 120 mg Drug Facts

Active ingredient (in each tablet)

Pseudoephedrine HCl 120 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
- 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 1 tablet every 12 hours• do not take more than 2 tablets in 24 hours
children under 12 years	do not use this product in children under 12 years of age

Other information

- **each tablet contains:** calcium 45 mg
- store at 20-25°C (68 - 77°F) in a dry place
- protect from light
- **do not use if blister unit is broken or torn**
- see carton end panel for lot number and expiration date
- this product meets the requirements of USP *Drug Release Test 3*

Inactive ingredients

carnauba wax, colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to Sudafed® Sinus Congestion 12 Hour active ingredient

Pseudoephedrine Hydrochloride Extended Release Tablets 120 mg

Nasal Decongestant

Maximum Strength – Non-Drowsy

Sinus Pressure – Congestion

10 COATED CAPLETS*

120 mg EACH

actual size

*(Capsule-shaped Tablets)

12 Hour Sinus



05492 RT C3


CODE AREA

OPEN OTHER END


Drug Facts		Drug Facts (continued)	
Active ingredient (in each tablet) Purpose Pseudoephedrine HCl 120 mg Nasal decongestant		Directions	
Uses <ul style="list-style-type: none"> ■ temporarily relieves nasal congestion due to the common cold, hay fever, or other upper respiratory allergies ■ temporarily relieves sinus congestion and pressure 		adults and children 12 years and over	<ul style="list-style-type: none"> ■ take 1 tablet every 12 hours ■ do not take more than 2 tablets in 24 hours
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 <ul style="list-style-type: none"> ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland 		children under 12 years	do not use this product in children under 12 years of age
Other information <ul style="list-style-type: none"> ■ each tablet contains: calcium 45 mg ■ store at 20-25°C (68-77°F) in a dry place ■ protect from light ■ do not use if blister unit is broken or torn ■ see caution panel for lot number and expiration date ■ this product meets the requirements of USP <i>Drug Release Test 3</i> 		Inactive ingredients carnauba wax, colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyorbate 80, titanium dioxide	
Questions or comments? 1-800-719-9280		Distributed By Perrigo® Allgen, MI 49010 • www.perrigo.com	

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

Convenient Reclosing Tab



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



N 3 45802-107-52 7

PSEUDOEPHEDRINE HYDROCHLORIDE

pseudoephedrine hcl tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45802-107
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII: 7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	

POLYSORBATE 80 (UNII: 6OZP39ZG8H)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	L054
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-107-52	10 in 1 CARTON	05/24/2014	
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
ANDA	ANDA075153	05/24/2014	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 11/2021

Padagis Israel Pharmaceuticals Ltd