

**NASAL DECONGESTANT- pseudoephedrine hydrochloride tablet, film coated, extended release**

**Rebel Distributors Corp**

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**Nasal Decongestant 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"> <li>• take 1 tablet every 12 hours</li> <li>• do not take more than 2 tablets in 24 hours</li> </ul>
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® 12 Hour Caplets active ingredient

Nasal Decongestant

MAXIMUM STRENGTH

NON-DROWSY

SINUS

pseudoephedrine hydrochloride extended release tablets, 120 mg

Long-Acting Nasal Decongestant

12-Hour

Sinus pressure

Congestion

Pseudoephedrine HCl

120 mg each

\*(Capsule-shaped Tablets)

**PHYSICIAN PARTNER<sub>x</sub>**  
A DIVISION OF REBEL DISTRIBUTORS CORP.

NDC 42254-359-10

**Nasal Decongestant 120mg**  
**#10 E.R. 12-Hour Tablet**

Each tablet contains: Pseudoephedrine HCl 120mg Nasal Decongestant

*Non-Drowsy / Sinus Pressure / Congestion*

Product ID: SN035910

Dist. By: AmerisourceBergen 1300 Morris Drive, Chesterbrook, PA 19087

Distributed by: Physician Partner, Thousand Oaks, CA 91320 [www.physicianpartner.com](http://www.physicianpartner.com)  
Store at controlled room temperature 15°-30°C (59°-86°F) Keep medication out of the reach of children.

**Peel**   **Peel**   **Peel**   **Peel**

Nasal Decongestant 120mg  
#10 E.R. 12-Hour Tablet   Rx# Master  
Lot #: 000000   Exp. Date: 00/00/00  
NDC 42254-359-10   AWP: \$17.98

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Exp. 00/00/00

0169C0NS

## NASAL DECONGESTANT

pseudoephedrine hydrochloride tablet, film coated, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42254-359(NDC:24385-054)
<b>Route of Administration</b>	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)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

**Product Characteristics**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42254-359-10	1 in 1 CARTON		
1		10 in 1 BLISTER PACK		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075153	08/12/1999	

**Labeler** - Rebel Distributors Corp (118802834)

**Registrant** - PSS World Medical, Inc. (101822862)

**Establishment**

Name	Address	ID/FEI	Business Operations
PSS World Medical, Inc.		791528623	REPACK(42254-359)

**Establishment**

Name	Address	ID/FEI	Business Operations
STAT RX USA LLC		786036330	REPACK(42254-359)

**Establishment**

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	RELABEL(42254-359) , REPACK(42254-359)

**Establishment**

Name	Address	ID/FEI	Business Operations
SCRIPT PAK		964420108	RELABEL(42254-359) , REPACK(42254-359)

**Establishment**

Name	Address	ID/FEI	Business Operations
Keltman Pharmaceuticals, Inc.		362861077	REPACK(42254-359)

## Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distirbutors Corp.		118802834	RELABEL(42254-359) , REPACK(42254-359)

Revised: 12/2012

Rebel Distributors Corp