

**TOPCARE 12 HOUR DECONGESTANT- pseudoephedrine hydrochloride tablet,  
film coated, extended release  
Topco Associates LLC**

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**Topco Associates LLC. 12 Hour 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?

**1-888-423-0139**

### Principal Display Panel

TopCare® health

COMPARE TO SUDAFED® SINUS CONGESTION 12 HOUR ACTIVE INGREDIENT

NON-DROWSY

12 Hour Decongestant

PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED RELEASE TABLETS, 120 mg

NASAL DECONGESTANT

MAXIMUM STRENGTH • SINUS

12 HOUR

- Sinus Pressure + Congestion

20 COATED CAPLETS\*

\*CAPSULE-SHAPED TABLETS

actual size

QUALITY GUARANTEED



\*This product is not manufactured or distributed by McNeil Consumer Healthcare Division of McNeil-PPC, Inc. distributor of Sudafed® Sinus Congestion 12 Hour.



**Drug Facts**

**Active ingredient (in each tablet)** Pseudoephedrine HCl 120 mg, 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 medicine or over-the-counter (OTC) drug 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 you are taking a prescription medicine or OTC drug, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- 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

- symptoms do not improve within 7 days or occur with a fever
- nervousness, dizziness, or sleepiness occur

If pregnant or breastfeeding, 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).

**Other information**

- each tablet contains calcium 45 mg
- store at 20-25°C (68-77°F) in a dry place
- product from 10 mg
- 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, poly sorbate 80, titanium dioxide

**Directions**

adults and children 12 years and over	take 1 tablet every 12 hours
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**Drug Facts (continued)**

**Directions**

- take 1 tablet every 12 hours
- do not take more than 2 tablets in 24 hours

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**Questions or comments?** 1-888-423-0139

Distributed By **Perrigo®** Allegan, MI 49010 PERA0521

Scan here for more information or call 1-888-423-0139

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# 12 Hour Decongestant

PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED RELEASE TABLETS, 120 mg NASAL DECONGESTANT

MAXIMUM STRENGTH • SINUS



COMPARE TO SUDAFED® SINUS CONGESTION 12 HOUR ACTIVE INGREDIENT\*\*

NON-DROWSY

# 12 Hour Decongestant

PSEUDOEPHEDRINE HYDROCHLORIDE EXTENDED RELEASE TABLETS, 120 mg NASAL DECONGESTANT

MAXIMUM STRENGTH • SINUS



• Sinus Pressure + Congestion

20 COATED CAPLETS\*  
\*CAPSULE-SHAPED TABLETS

actual size



NDC 36800-054-60



# TOPCARE 12 HOUR DECONGESTANT

pseudoephedrine hydrochloride tablet, film coated, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-054
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	L054
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-054-52	10 in 1 CARTON	04/25/2000	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:36800-054-60	20 in 1 CARTON	05/20/2003	
3		1 in 1 BLISTER PACK; Type 0: Not a Combination		

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Product

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075153	04/25/2000	

**Labeler** - Topco Associates LLC (006935977)

Revised: 10/2022

Topco Associates LLC