

**TOPCARE NIGHTTIME COLD AND FLU SIMPLE RELIEF- choline salicylate,
diphenhydramine hydrochloride, phenylephrine hydrochloride liquid
TOPCO ASSOCIATES LLC**

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.

TOP CARE NIGHTTIME COLD AND FLU SIMPLE RELIEF

TopCare Nighttime Cold & Flu Simple Relief

(choline salicylate, diphenhydramine hcl, phenylephrine hcl), solution

Topco Associates LLC

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Topco Associates LLC. Nighttime Cold & Flu Simple Relief

Drug Facts

Active ingredients (in each 30 mL)

Choline Salicylate (NSAID)* 870 mg

Diphenhydramine HCl 50mg

Phenylephrine HCl 10 mg

Purpose

Pain reliever/fever reducer

Antihistamine

Nasal decongestant

nonsteroidal anti-inflammatory drug*

Uses

temporarily relieves these common cold and flu symptoms:

- nasal congestion
- minor aches and pains
- runny nose
- sneezing
- watery eyes
- sore throat
- headache
- temporarily reduces fever

Warnings

Reye's syndrome

Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert

Salicylates (NSAIDs) may cause a severe allergic reaction which may include:

- hives
- rash
- shock
- skin reddening
- facial swelling ▪ asthma (wheezing)

Stomach bleeding warnings

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- if you have ever had an allergic reaction to salicylates (including aspirin) or any other pain reliever / fever reducer.
- with any other drug containing diphenhydramine, even one used on the skin
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or 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.
- in children under 12 years of age

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn or if you have ulcers or bleeding problems
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, diabetes, thyroid disease, or glaucoma

- you have a cough with excessive phlegm (mucus)
- you have difficulty in urination due to enlargement of the prostate gland
- you have breathing problems such as emphysema or chronic bronchitis
- you have a persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for anticoagulation (thinning the blood), diabetes, gout, or arthritis.
- taking a diuretic
- under a doctor's care for any serious condition
- taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or a loss of hearing occurs
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.
- nervousness, dizziness, or sleeplessness occurs
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use salicylates (NSAIDs) during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- do not exceed recommended dosage.
- do not take more than 6 doses in any 24-hour period.
- use enclosed dose cup
- keep dosage cup with product
- mL = milliliters
- adults and children 12 years of age and over: 30mL every 4 hours
- children under 12 years of age: do not use

Other information

- each 30mL contains: **Sodium 16 mg**
- tamper evident: Do not use if foil seal under cap is broken or missing.
- read all product information before using
- store at 68° to 86°F (20° to 30°C)
- avoid excessive heat and humidity

Inactive ingredients

citric acid anhydrous, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol

Questions or Comments?

Call 1-888-423-0139

PRINCIPAL DISPLAY PANEL

NDC 36800-888-08

Nighttime

Cold & Flu

Simple Relief

8 FL OZ (237mL)

NDC 36800-888-08

TopCare®

Nighttime Cold & Flu Simple Relief™

- Pain Reliever/Fever Reducer (NSAID)
Choline Salicylate 870mg
- Antihistamine
Diphenhydramine HCl 50mg
- Nasal Decongestant
Phenylephrine HCl 10mg

Relieves:

- Aches • Fever • Sore Throat
- Runny Nose
- Nasal Congestion
- Watery Eyes • Sneezing

Dye Free • Sugar Free • Alcohol Free
Gluten Free • Flavor Free • Acetaminophen Free



8 FL OZ (237mL)

LIFT HERE FOR
DRUG FACTS

Drug Facts (continued)

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- adults and children 12 years and over: 30 mL every 4 hours
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Other information

- each 30 mL contains:
 - Sodium 16 mg
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- store at room temperature 68-86°F (20-30°C)
- avoid excessive heat and humidity

Drug Facts (continued)

Inactive ingredients
anhydrous citric acid, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium saccharin, sorbitol

Questions or comments?
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Tamper evident: do not use if foil seal under cap is broken or missing

Dose every 4 hours.

DISTRIBUTED BY
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QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com



This Top Care® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.



R062616M
KEEP LEAFLET AFTER OPENING

Drug Facts

Active ingredients Purpose (in each 30 mL)

Choline Salicylate (NSAID)* 870 mg
..... Pain reliever / fever reducer

Diphenhydramine HCl 50 mg
..... Antihistamine

Phenylephrine HCl 10 mg
..... Nasal decongestant

* nonsteroidal anti-inflammatory drug

Uses

Temporarily relieves these common cold and flu symptoms:

- nasal congestion • minor aches and pains
- sore throat • headache • runny nose
- sneezing • watery eyes
- temporarily reduces fever

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Salicylates (NSAIDs) may

Drug Facts (continued)

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- skin reddening • facial swelling
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Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

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Drug Facts (continued)

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Ask a doctor before use if

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- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, diabetes, thyroid disease, or glaucoma
- you have a cough with excessive phlegm (mucus)
- you have difficulty in urination due to enlargement of the prostate gland
- you have difficulty in urination due

Drug Facts (continued)

to enlargement of the prostate gland

- you have breathing problems such as emphysema or chronic bronchitis
- you have persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for anti-coagulation (thinning the blood), diabetes, gout, or arthritis.
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TOPCARE NIGHTTIME COLD AND FLU SIMPLE RELIEF

choline salicylate, diphenhydramine hydrochloride, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-888
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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CHOLINE SALICYLATE (UNII: KD510K1QW) (SALICYLIC ACID - UNII:O414PZ4LPZ)	CHOLINE SALICYLATE	870 mg in 1 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-888-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/06/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	09/06/2016	

Labeler - TOPCO ASSOCIATES LLC (006935977)

Revised: 6/2018

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