

TOPCARE NITE TIME COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

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.

Topco Associates LLC. Nite Time Cold & Flu Drug Facts

Active ingredients (in each liquid cap)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: If sore throat is severe, lasts for more than 2 days, is accompanied or followed

by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- pain or cough 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
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- take only as directed – see overdose warning
- do not exceed 4 doses per 24 hours

adults & children 12 yrs & over	2 liquid caps with water every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Inactive ingredients

edible dye-free ink*, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution *may contain this ingredient

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

COMPARE TO VICKS® NYQUIL® COLD & FLU ACTIVE INGREDIENTS

MULTI-SYMPTOM RELIEF

Nite Time Cold & Flu Relief

OUR PHARMACISTS RECOMMEND

PAIN RELIEVER-FEVER REDUCER - ACETAMINOPHEN

COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr • ANTIHISTAMINE – DOXYLAMINE SUCCINATE

DYE-FREE

Headache, Fever, Sore Throat, Minor Aches & Pains

Sneezing, Runny Nose • Cough

Free of Artificial Dyes and Preservatives

Alcohol Free

16 LIQUID CAPS

actual size

**This product is not manufactured or distributed by Procter & Gamble, distributor of Vicks® NyQuil® Cold & Flu.

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ELK GROVE VILLAGE, IL 60007
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QUESTIONS? 1-888-423-0139
topcare@topco.com
www.topcarebrand.com
MADE IN CANADA

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org



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



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NDC 36800-614-73



COMPARE TO VICKS®
NYQUIL® COLD & FLU
ACTIVE INGREDIENTS**

MULTI-SYMPTOM RELIEF

**NiteTime
Cold & Flu Relief**

PAIN RELIEVER-FEVER REDUCER - ACETAMINOPHEN
COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr • ANTIHISTAMINE - DOXYLAMINE SUCCINATE

DYE-FREE

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Sneezing, Runny Nose • Cough



Free of Artificial Dyes and Preservatives
Alcohol Free

16 LIQUID CAPS

actual size



CONVENIENT RECLOSEING TAB

Drug Facts

DO NOT USE IF BLISTER UNIT IS BROKEN OR TORN

Active Ingredients (in each liquid cap)

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Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 15 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine

Uses: temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- minor aches and pains
- runny nose and sneezing
- sore throat
- headache
- fever

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■ if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have ■ liver disease ■ glaucoma

- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

- taking acetaminophen or aspirin
- taking the blood thinning drug warfarin

Drug Facts (continued)

Questions or comments? 1-888-423-0139

Store at 20°-25° C (68°-77°F).



GLUTEN FREE

if used as directed

2 liquid caps with water a day (16 caps)

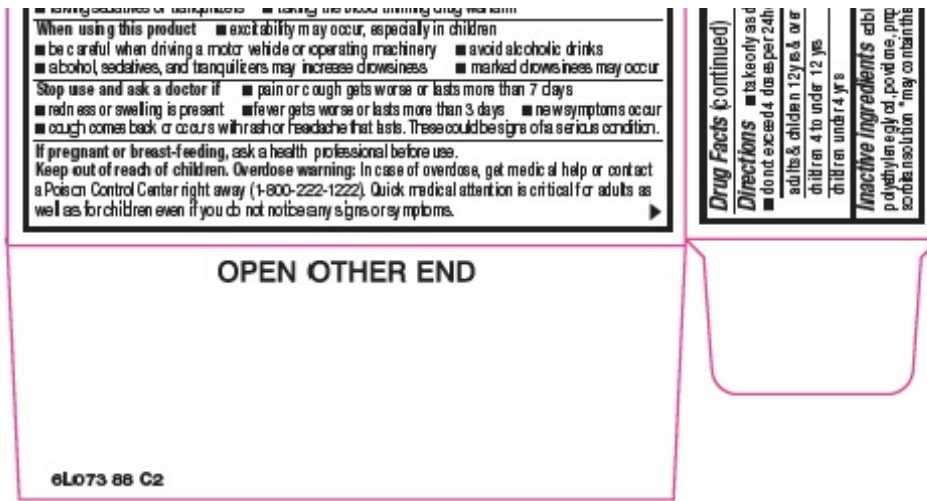
ask a doctor

do not use

acetaminophen, guaifenesin, glycerin,

when glycol, purified water, sodium

ingredients



TOPCARE NITE TIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-614
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	YELLOW (clear)	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	6L0
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-614-73	8 in 1 CARTON	08/01/2017	
1		2 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	08/01/2017	

Labeler - Topco Associates LLC (006935977)

Revised: 12/2019

Topco Associates LLC