

**TOPCARE NITE TIME COLD AND FLU RELIEF- acetaminophen,
dextromethorphan hbr, doxylamine succinate solution
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 Relief Drug Facts

Active ingredients (in each 30 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses

temporarily relieves common cold/flu symptoms:

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

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, occurs with or is 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)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- a sodium-restricted diet

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
- only use the dose cup provided
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

Other information

- **each 30 mL contains:** sodium 38 mg
- store at 20- 25°C (68- 77°F)

Inactive ingredients

alcohol, anhydrous citric acid, D&C yellow no. 10, FD&C green no. 3, FD&C yellow no. 6, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Question?

1-888-423-0139

Package/Label Principal Display Panel

TopCare® health

COMPARE TO VICKS® NYQUIL® ACTIVE INGREDIENTS

MULTI-SYMPTOM RELIEF

Nite Time Cold & Flu Relief

PAIN RELIEVER-FEVER REDUCER – ACETAMINOPHEN

COUGH SUPPRESSANT – DEXTROMETHORPHAN HBr

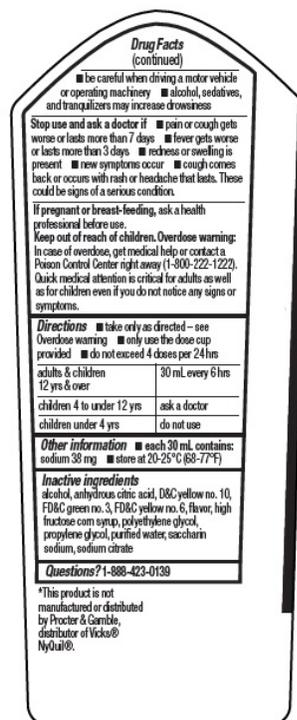
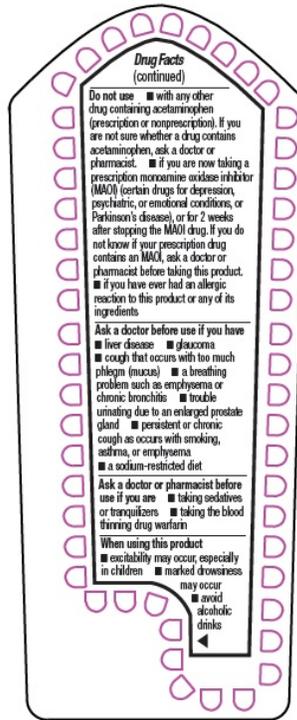
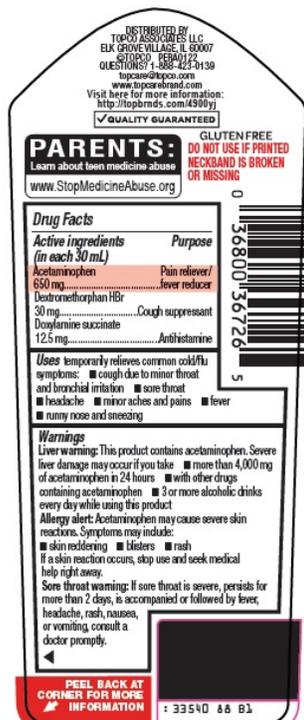
ANTIHISTAMINE – DOXYLAMINE SUCCINATE

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

ALCOHOL 10%

12 FL OZ (355 mL)

ORIGINAL FLAVOR



TOPCARE NITE TIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-335
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

Product Characteristics

Color	GREEN (clear, bright green)	Score	
Shape		Size	
Flavor	FRUIT (anise / cooling menthol aroma)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-335-38	296 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/18/2011	09/27/2013
2	NDC:36800-335-30	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/22/2011	11/27/2013
3	NDC:36800-335-34	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/17/2012	
4	NDC:36800-335-40	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/16/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/18/2011	

Labeler - Topco Associates LLC (006935977)