TOPCARE NITE TIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate solution
Topco Associates LLC

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
- 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, persists 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
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough as occurs with smoking, asthma, or emphysema

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 35 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

Questions?

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

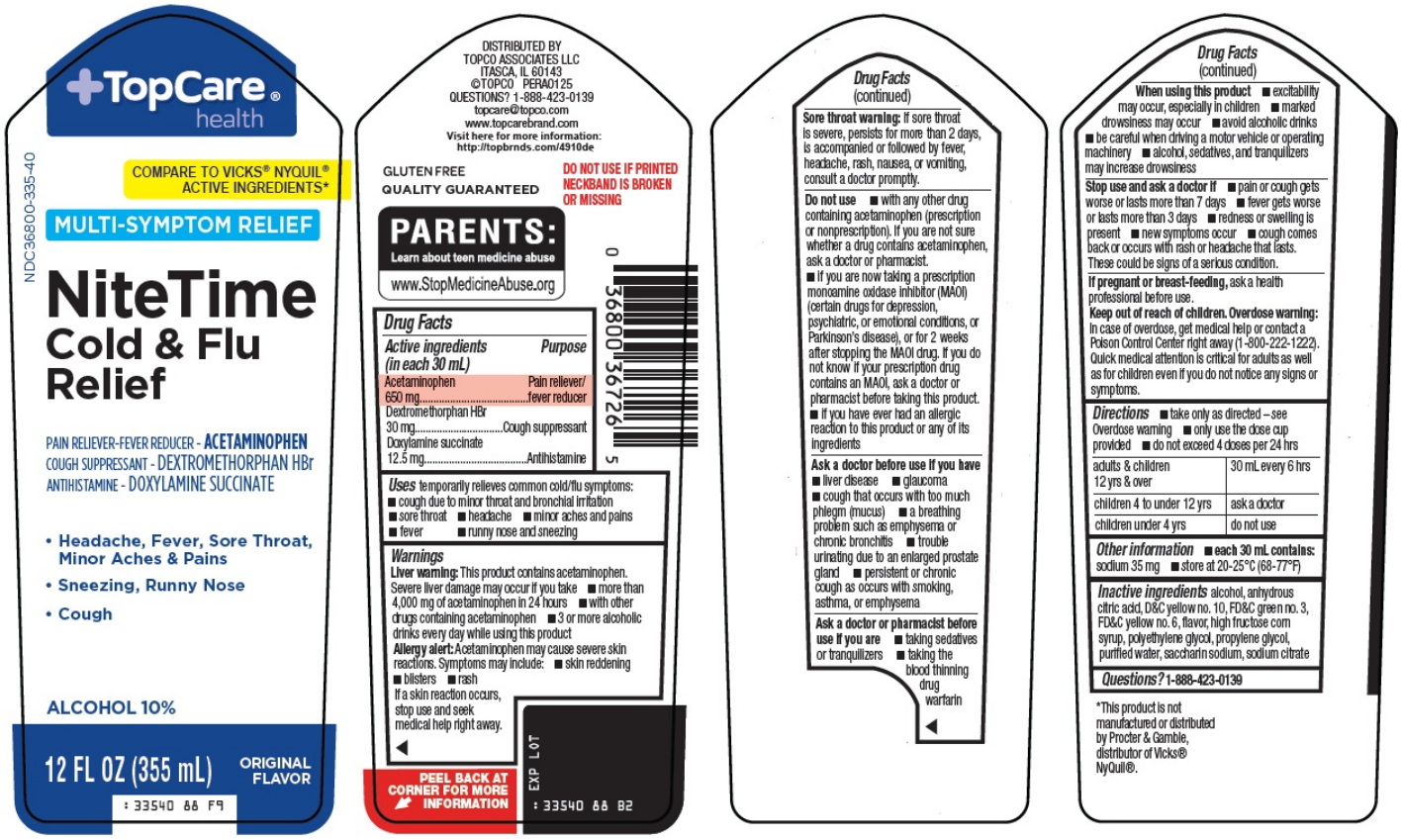
• Sneezing, Runny Nose

• 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: V9BI9B5YI2) (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: 3WQ0SDW1A)	
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 Drug	M012	08/18/2011	

Labeler - Topco Associates LLC (006935977)

Revised: 1/2026 Topco Associates LLC