NITE TIME COLD FLU RELIEF- acetaminophen,dextromethorphan hbr, doxylamine succinate liquid
We Care Distributor Inc.

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.

NiteTime Cold and Flu Drug Facts

Active ingredient (in each 15 mL tablespoon)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

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

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 4 doses. Severe liver damage may occur if adult/child takes:

- 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

Sore throat warning: If sore throat is severe, persists for more than two 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

- to make a child sleepy

Ask a doctor before use if you have
- liver disease
- glaucoma
- a sodium-restricted diet
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or occurs with smoking, asthma chronic bronchitis or emphysema

Ask a doctor or pharmacist before use if you are
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product
- do not use more than directed
- 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
- redness or swelling is present
- pain or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- 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: Taking more than recommended dose may cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt 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)**
- **use dose cup**
- **do not exceed 4 doses per 24 hours**

adults and children 12 years and over	30 mL every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years	do not use

- when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

Other information

- each 15 mL (tablespoon) contains: sodium 46 mg
- store at 15°-30°C (59°-86°F)
- protect from freezing

Inactive ingredients

alcohol, 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, sodium benzoate

Questions or comments?

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

Principal Display Panel

See New Warnings Information

Compare to NyQuil® Cold & Flu Active Ingredients

NiteTime

Cold & Flu

Pain Reliever, Fever Reducer, Cough Suppressant, Antihistamine

Multi-Symptom Relief

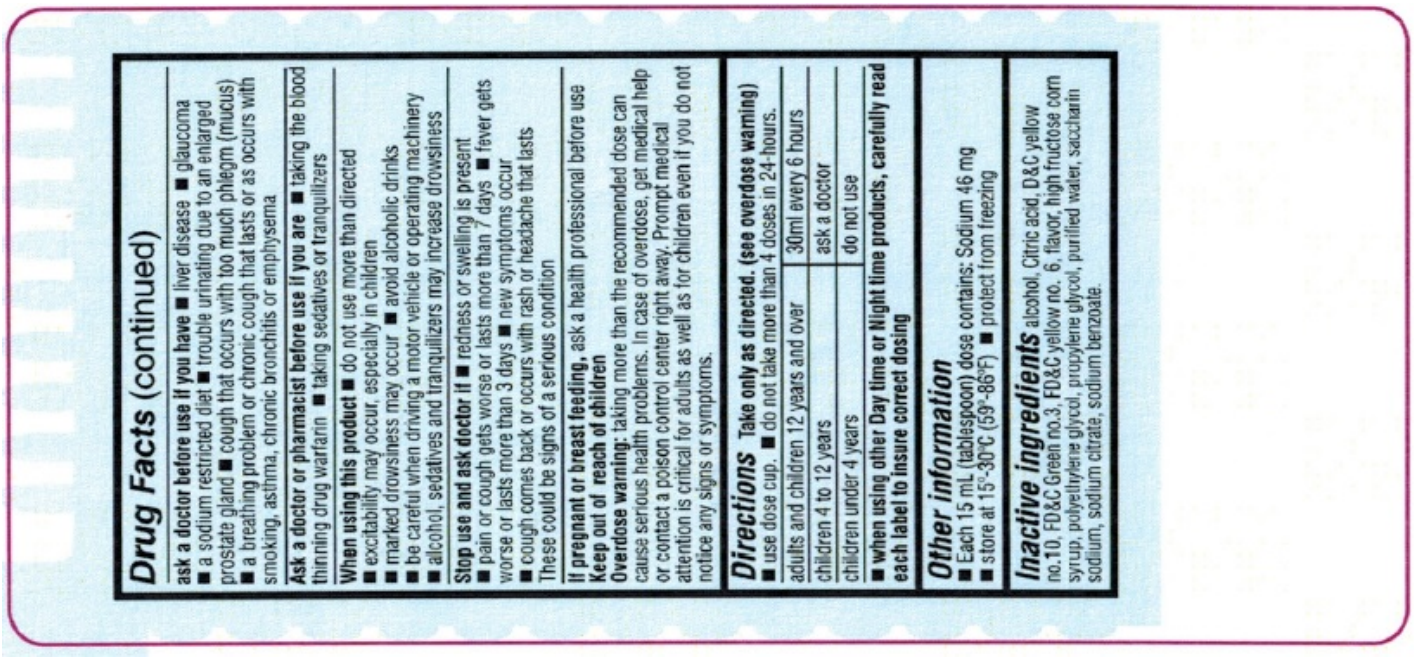
Aches, Fever - Acetaminophen

Cough - Dextromethorphan HBr

Sneezing, Runny Nose - Doxylamine Succinate

Original Flavor

10% Alcohol



Drug Facts (continued)

ask a doctor before use if you have ■ liver disease ■ glaucoma ■ a sodium restricted diet ■ trouble urinating due to an enlarged prostate gland ■ cough that occurs with too much phlegm (mucus) ■ a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis or emphysema

Ask a doctor or pharmacist before use if you are ■ taking the blood thinning drug warfarin ■ taking sedatives or tranquilizers

When using this product ■ do not use more than directed ■ 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 doctor if ■ redness or swelling is present ■ pain or cough gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ new symptoms occur ■ cough comes back or occurs with rash or headache that lasts These could be signs of a serious condition

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Other information

■ Each 15 mL (tablespoon) dose contains: Sodium 46 mg ■ store at 15°-30°C (59°-86°F) ■ protect from freezing

Inactive ingredients alcohol, 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, sodium benzoate.

NITE TIME COLD FLU RELIEF

acetaminophen,dextromethorphan hbr, doxylamine succinate liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70005-046
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 15 mL
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg in 15 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 (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

SODIUM BENZOATE (UNII: OJ245FE5EU)	

Product Characteristics			
Color	GREEN (Bright)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-046-01	1 in 1 CARTON	08/10/2016	
1		120 mL in 1 BOTTLE; 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	08/10/2016	

Labeler - We Care Distributor Inc. (079832998)

Establishment

Name	Address	ID/FEI	Business Operations
PURINE PHARMA LLC		019950491	manufacture(70005-046)

Revised: 8/2016 We Care Distributor Inc.