NIGHTTIME- acetaminophen, dextromethorphan hydrobromide and doxylamine succinate liquid
CVS Pharmacy

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.

CVS Pharmacy, Inc. NightTime Cold/Flu Relief Drug Facts

Active ingredients (in each 30 ml dose cup)

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. The maximum daily dose of this product is 4 doses (2,600 mg acetaminophen) in 24 hours. 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

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.
- to make a child sleepy
- 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
- 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.

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 Liver warning

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

adults & children 12 yrs & over	30 ml (2 TBSP) every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

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

Other information

- each 30 ml dose cup contains: sodium 38 mg
- store at 20-25°C (68-77°F)

Inactive ingredients

alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to the active ingredients in Vicks® NyQuil®

Multi-Symptom

NIGHTTIME COLD/FLU RELIEF

CHERRY FLAVOR

Pain reliever, Fever reducer, Cough suppressant, Antihistamine

Acetaminophen - aches, fever, sore throat

Dextromethorphan HBr - cough

Doxylamine Succinate - sneezing, runny nose

ALCOHOL 10%

NIGHTTIME

acetaminophen, dextromethorphan hbr, doxylamine succinate liquid

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:59779-459
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (DEXTROMETHORPHAN)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL
DOXYLAMINE SUCCINATE (DOXYLAMINE)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL	
ANHYDROUS CITRIC ACID	
FD&C BLUE NO. 1	
FD&C RED NO. 40	
HIGH FRUCTOSE CORN SYRUP	
POLYETHYLENE GLYCOLS	
PROPYLENE GLYCOL	
WATER	
SACCHARIN SODIUM	

SODIUM CITRATE	

Product Characteristics

Color	RED (Clear/Dark Red)	**Score**	
Shape		**Size**	
Flavor	CHERRY (Menthol Aroma)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-459-38	295 mL in 1 BOTTLE		
2	NDC:59779-459-30	177 mL in 1 BOTTLE		
3	NDC:59779-459-40	355 mL in 1 BOTTLE		
4	NDC:59779-459-34	237 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/12/2011	

Labeler - CVS Pharmacy (062312574)

Revised: 11/2012 CVS Pharmacy