NIGHTTIME COLD AND FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled Chain Drug Consortium, LLC

Safeway Nighttime Cold & Flu

Active Ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine Succinate 6.25 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Antihistimine

Purpose

Pain reliever / fever reducer

Cough suppressant

Antihistamine

Uses

- temporarily relieves common cold and flu symptoms:
 - sore throat
 - headache
 - minor aches and pains
 - fever
 - runny nose and sneezing
 - cough due to minor throat and bronchial irritation

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 of pharmacist before taking this product.

Ask a doctor before use if you have

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

Ask a doctor of pharmacist before use if you are

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

When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children
- avoid alcoholic drinks
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

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: Taking more than the recommended dose can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1888-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than directed (see Overdose warning)
- do not take more than 4 doses in 24 hours
- adults and children 12 years and over: take 2 softgels with water every 6 hours
- swallow whole; do not crush, chew, or dissolve
- children under 12 years: do not use
- when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

Other Information

- store between 15-30°C (59-86°F)
- avoid excessive heat

Inactive Ingredients

D&C yellow #10, FD&C blue #1, gelatin, glycerin, lecithin, light mineral oil, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

Questions or Comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

*COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® NYQUIL® & FLU LIQUICAPS®

Nighttime, Multi-Symptom

Cold & Flu Relief

ACETAMINOPHEN 325 mg

Pain reliever/Fever reducer

DEXTROMETHORPHAN HBr 15 mg

Cough Suppressant

DOXYLAMINE SUCCINATE 6.25 mg

Antihistamine

Relieves: Aches • Fever • SoreThroat Cough • Runny Nose • Sneezing

Alcohol-Free

Softgels**

(**Liquid-Filled Capsules)

*This product is not manufactured or distributed by The Procter & Gamble Company. Vicks \$, NyQuil\$, and LiquiCaps \$ are registered trademarks of The Procter & Gamble Company

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed By: Pharmacy Value Alliance, LLC

407 East Lancaster Avenue,

Wayne, PA 19087

Package Label

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Drug Facts (continued)

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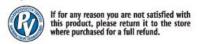




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PREMIER VALUE Cold & Flu Relief

NIGHTTIME COLD AND FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68016-798

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE (UNII: FZ 989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SORBITAN (UNII: 6092ICV9RU)		
SORBITOL (UNII: 506T60A25R)		
MANNITOL (UNII: 30WL53L36A)		
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)		
LIGHT MINERAL OIL (UNII: N6K5787QVP)		

Product Characteristics				
Color	green	Score	no score	
Shape	OVAL	Size	21mm	

Flavor	Imprint Code	PC10
Contains		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-798- 16	16 in 1 CARTON	09/15/2022	
1		1 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 Drug	M012	09/15/2022	

Labeler - Chain Drug Consortium, LLC (101668460)

Revised: 3/2024 Chain Drug Consortium, LLC