DAY-TIME NIGHT-TIME- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl
Chain Drug Consortium, 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.

DRUG FACTS

Active ingredients for Night-Time (in each softgel)

Acetaminophen 325 mg

Dextromethorphan Hydrobromide 15 mg

Doxylamine succinate 6.25 mg

Active ingredients for Day-Time (in each softgel)

Acetaminophen 325 mg, USP

Dextromethorphan Hydrobromide 10 mg

Phenylephrine HCl 5 mg

Purpose for Nighttime

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Purpose for Daytime

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- minor aches and pains
- sore throat pain
- fever
- headache
- muscular aches
- nasal congestion (Day-Time only)
- runny nose and sneezing (Night-Time only)
- cough due to minor throat and bronchial irritation(Night- Time only)

Warnings

Liver warning: These products contain acetaminophen. Severe liver damage may occur if you take

- more than 6 doses in 24 hours (Night-Time), which is the maximum daily amount
- more than 6 doses in 24 hours (Day-Time), which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using these products

Sore throat warning: If sore throat is severe, lasts for more than 2 days, occurs with or is followed by fever, rash, nausea, or vomiting, consult a doctor promptly.

Overdose warning: **Taking more than the recommended dose (overdose) could 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 children even if you do not notice any signs or symptoms

Do not use
- with other drugs 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 sleep

Ask a doctor before using if you have
- liver disease
- heart disease
- asthma
- emphysema
- thyroid disease
- diabetes
- high blood pressure
- cough with excessive phlegm (mucus)
- breathing problems
- chronic bronchitis
- persistent or chronic cough
- cough associated with smoking
- trouble urinating due to enlarged prostate gland
- glaucoma (Night-Time only)

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

When using this product
- **do not use more than directed, in addition when using Night-Time:**
- 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
- **do not use with other products containing acetaminophen**

Stop use and ask a doctor if

- swelling or redness is present
- symptoms do not get better within 7 days or are accompanied by a fever
- you get nervous, dizzy or sleepless
- fever gets worse or lasts more than 3 days
- new symptoms occur
- cough lasts more than 7 days (adults) or 5 days (children), recurs or is accompanied by fever, rash, or persistent headache. These may be signs of a serious condition.

If pregnant or breast-feeding,

ask a health care professional before use.

Keep out of reach of children.

Directions
- take only as recommended (see overdose warning)
- take Night-Time or Day-Time

age	Night-Time	Day-Time
adults and children 12 years of age and older	swallow 2 softgels with water every 6 hours	swallow 2 softgels with water every 4 hours
children 4 to 12 years of age	ask a doctor	ask a doctor
children under 4 years of age	**do not use**	**do not use**

- **If taking Night-Time and Day-Time softgels limit total to 4 doses per day**

Other information
- store at room temperature 15°-30°C (59°-86° F) and avoid excessive heat
- this product does not contain phenylpropanolamine (PPA)
- *This product is not manufactured or distributed by Procter & Gamble, owner of the registered trademark Vicks® Dayquil® and Vicks® Nyquil®

Inactive ingredients

Night-Time D&C Yellow #10, FD&C Blue #1, gelatin, glycerin, polyethylene glycol 400 NF, *polyethylene glycol (PEG)- 600, povidone, propylene glycol USP, purified water USP, sorbitan, sorbitol and white edible ink. *May also contain

Day-Time * butylated hydroxyanisole, *butylated hydroxytoluene, *carmine, *D&C yellow #10, FD&C Red#40, FD&C yellow #6, gelatin, glycerin USP, *mannitol, polyethylene glycol 400 NF, *polyethylene glycol 600, povidone, propylene glycol USP, purified water USP, *sodium metabisulfite, *sorbitan, *sorbitol, sorbitol special, and white edible ink. *May also contain.

Questions or comments?

call toll free **1-877-753-3935**

Principal Display Panel

*Compare to active ingredients in Vicks® Dayquil® & Nyquil®

SEE NEW WARNINGS INFORMATION

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

DISTRIBUTED BY:

CHAIN DRUG CONSORTIUM, LLC.

2300 NW CORPORATE BLVD., SUITE 115

BOCA RATON, FL 33431

Product Label

Multi symptom Day-Time Night-Time

DAY-TIME NIGHT-TIME

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68016-490

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68016-490-40	1 in 1 CARTON; Type 0: Not a Combination Product		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	2 BLISTER PACK	20
Part 2	2 BLISTER PACK	20

Part 1 of 2

NIGHT-TIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	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 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
POVIDONES (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	

SORBITOL (UNII: 506T60A25R)	

Product Characteristics			
Color	GREEN	**Score**	no score
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	P30;94A;35A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		10 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 FINAL	part341		

Part 2 of 2

DAY-TIME

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	

MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
POVIDONES (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	ORANGE (red)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	P19;95A;36A
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		10 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 FINAL	part341	07/12/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/12/2010	

Labeler - Chain Drug Consortium, LLC (101668460)

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