DAY TIME NIGHT TIME COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl Walgreens Company

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.

Daytime and Nighttime Cold and Flu Drug Facts

Active ingredients for DAYTIME (in each liquid cap)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Active ingredients for NIGHTTIME (in each liquid cap)

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

Purpose (DAYTIME ONLY)

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Purpose (NIGHTTIME ONLY)

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Uses (DAYTIME ONLY)

- temporarily relieves common cold/flu syptoms:
- nasal congestion
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever

Uses (NIGHTTIME ONLY)

- 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 (DAYTIME ONLY)

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4 in 24 hrs, which is the maximum daily amount for this product
- 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, see 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.

Ask a doctor before use if you have

- liver disease
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma or emphysema

Ask a doctor or pharmacist before use if you are

• taking the blood thinning drug warfarin

When using this product

• do not use more than directed

Stop use and ask doctor if

- you get nervous, dizzy or sleepless
- symptoms get worse or lasts more than 5 days (children) or 7 days (adults)
- 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 directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults and for children even if you do not notice any signs or symptoms.

Warnings (NIGHTTIME ONLY)

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4 doses in 24 hrs, which is the maximum daily amount for this product
- 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, see 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 sleep

Ask a doctor before use if you have

- liver disease
- glaucoma
- 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
- trouble urinating due to an enlarged prostate gland

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
- 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

- 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 directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults and for children even if you do not notice any signs or symptoms.

Directions (DAYTIME ONLY)

- take only as directed see Overdose warning
- do exceed more than 4 doses per 24 hrs

adults & children 12 years and over 2 capsules with water every 4 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 ensure correct dosing.

Directions (NIGHTTIME)

- take only as directed see Overdose warning
- do not exceed 4 doses per 24 hrs
- adults and children 12 years and over

adults & children 12 yrs & over 2 capsules with water 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 ensure correct dosing.

Other Information

- store at controlled room temperature 15°C to 30°C (59°F to 86°F)
- see end flap for expiration date and lot number

Inactive ingredients (DAYTIME ONLY)

FD&C red #40, FD&C yellow #6*, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, white ink

Inactive ingredients (NIGHTTIME)

D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, white ink

Questions or comments?

Principal Display Panel

Combo Pack

MULTI-SYMPTOM NON-DROWSY • DAYTIME

Cold & Flu

Acetaminophen

Aches/Fever/Sore Throat

Dextromethorphan HBr/Cough

Phenylephrine HCl/Nasal Congestion

32 LIQUID CAPS

MULTI-SYMPTOM • NIGHTTIME

Cold & Flu

Aches/Fever/Sore Throat

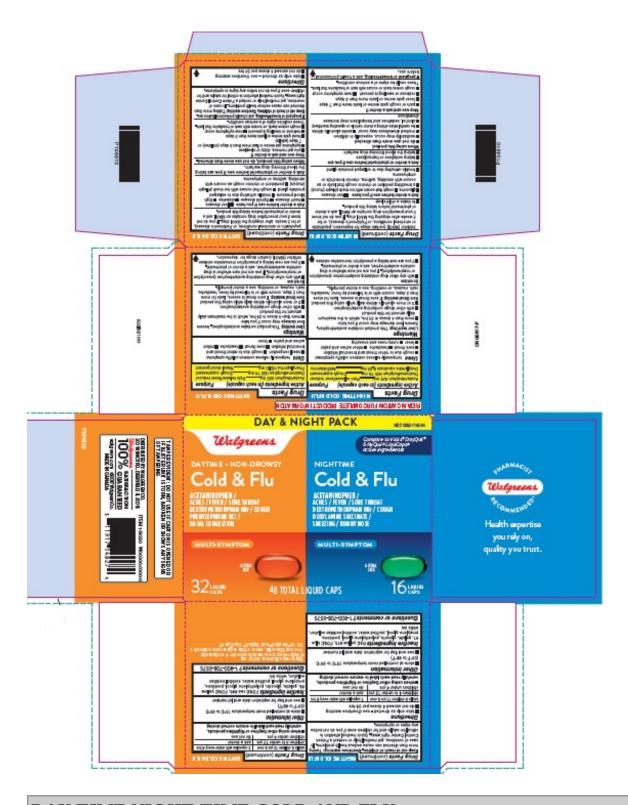
Dextromethorphan HBr/Cough

Doxylamine Succinate/Sneezing/Runny Nose

16 LIQUID CAPS

Compare to Vicks® DayQuil® & NyQuil® LiquiCaps® active ingredients‡‡

48 TOTAL LIQUID CAPS



DAY TIME NIGHT TIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information	1		
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-1142
Packaging			
# Item Code	Package Description	Mankating Start Da	to Marketing End Date
# Item Code	Package Description	Marketing Start Da	te Marketing End Date

Quant	Quantity of Parts			
Part #	Package Quantity	Total Product Quantity		
Part 1	4 BLISTER PACK	32		
Part 2	2 BLISTER PACK	16		

Part 1 of 2

DAY TIME COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	325 mg		
DEXTRO METHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII: 7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients			
Ingredient Name	Strength		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
PO VIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			

Product Characteristics				
Color	ORANGE	Score	no score	
Shape	OVAL	Size	20 mm	
Flavor		Imprint Code	95A	
Contains				

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	8 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	07/10/2017	03/01/2021

Part 2 of 2

NIGHT TIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	325 mg		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg		
DO XYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DO XYLAMINE - 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)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PO VIDO NE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

1 Todact Characteristics	Product Characteristics					
Color	GREEN	Score	no score			
Shape	OVAL	Size	20 mm			
Flavor		Imprint Code	35A			
Contains						

Packaging					
# Item Code		Package Description	Marketing Start Date	Marketing End Date	
1	8 in 1 E	BLISTER PACK; Type 0: Not a Combination Product			
Marketing Information					
Marketing Cat	tegory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph	final	part341	07/10/2017	03/01/2021	
Marketing Information					
Marketing Cat	tegory	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph	final	part341	07/10/2017	03/01/2021	

Labeler - Walgreens Company (008965063)

Revised: 3/2020 Walgreens Company