COLD AND FLU DAYTIME, NIGHTTIME, MULTI-SYMPTOM- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl Walgreens

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Walgreens Non-Drowsy Daytime & Nighttime Cold and Flu

Active ingredients (in each liquid-filled capsule) (Daytime Cold & Flu)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Nasal decongestant

Active ingredients (in each liquid-filled capsule) (Nighttime Cold & Flu)

Acetaminophen 325 mg
Dextromethorphan HBr 15 mg
Doxylamine succinate 6.25 mg

Purpose

Pain reliever/fever reducer
Cough suppressant
Antihistamine

Uses

- temporarily relieves common cold and flu symptoms:
  - fever
  - headache
  - sore throat
  - minor aches and pains
  - cough due to minor throat and bronchial irritation
  - nasal congestion ***(Daytime only)***
  - runny nose and sneezing ***(Nighttime only)***

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 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 ***(Nighttime only)***

Ask a doctor before use if you have
- cough that occurs with too much phlegm (mucus)
- liver disease
- difficulty in urination due to enlargement of the prostate gland
- heart disease ***(Daytime only)***
- diabetes ***(Daytime only)***
- thyroid disease ***(Daytime only)***
- high blood pressure ***(Daytime only)***
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema ***(Daytime only)***
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema ***(Nighttime only)***
- glaucoma ***(Nighttime only)***

Ask a doctor or pharmacist before use if you are
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers ***(Nighttime only)***

When using this product
- **do not exceed recommended dosage**
- excitability may occur, especially in children ***(Nighttime only)***
- avoid alcoholic beverages ***(Nighttime only)***
- marked drowsiness may occur ***(Nighttime only)***
- alcohol, sedatives, and tranquilizers may increase drowsiness ***(Nighttime only)***

- use caution when driving a motor vehicle or operating machinery ***(Nighttime only)***

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur ***(Daytime only)***
- pain, nasal congestion, or cough gets worse or lasts more than 7 days ***(Daytime only)***
- pain or cough gets worse or lasts more than 7 days ***(Nighttime only)***
- 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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

If taking NIGHTTIME and DAYTIME products, carefully read each section to ensure correct dosing.

Directions (Daytime only)

- **do not take more than directed**
- do not take more than 8 capsules per 24 hours
- adults and children 12 years and over: take 2 capsules with water every 4 hours
- children under 12 years: ask a doctor

Directions (Nighttime only)

- **do not take more than directed**
- do not take more than 8 capsules per 24 hours
- adults and children 12 years and over: take 2 capsules with water every 6 hours
- children under 12 years: ask a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- protect from heat, humidity and light
- 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, titanium dioxide

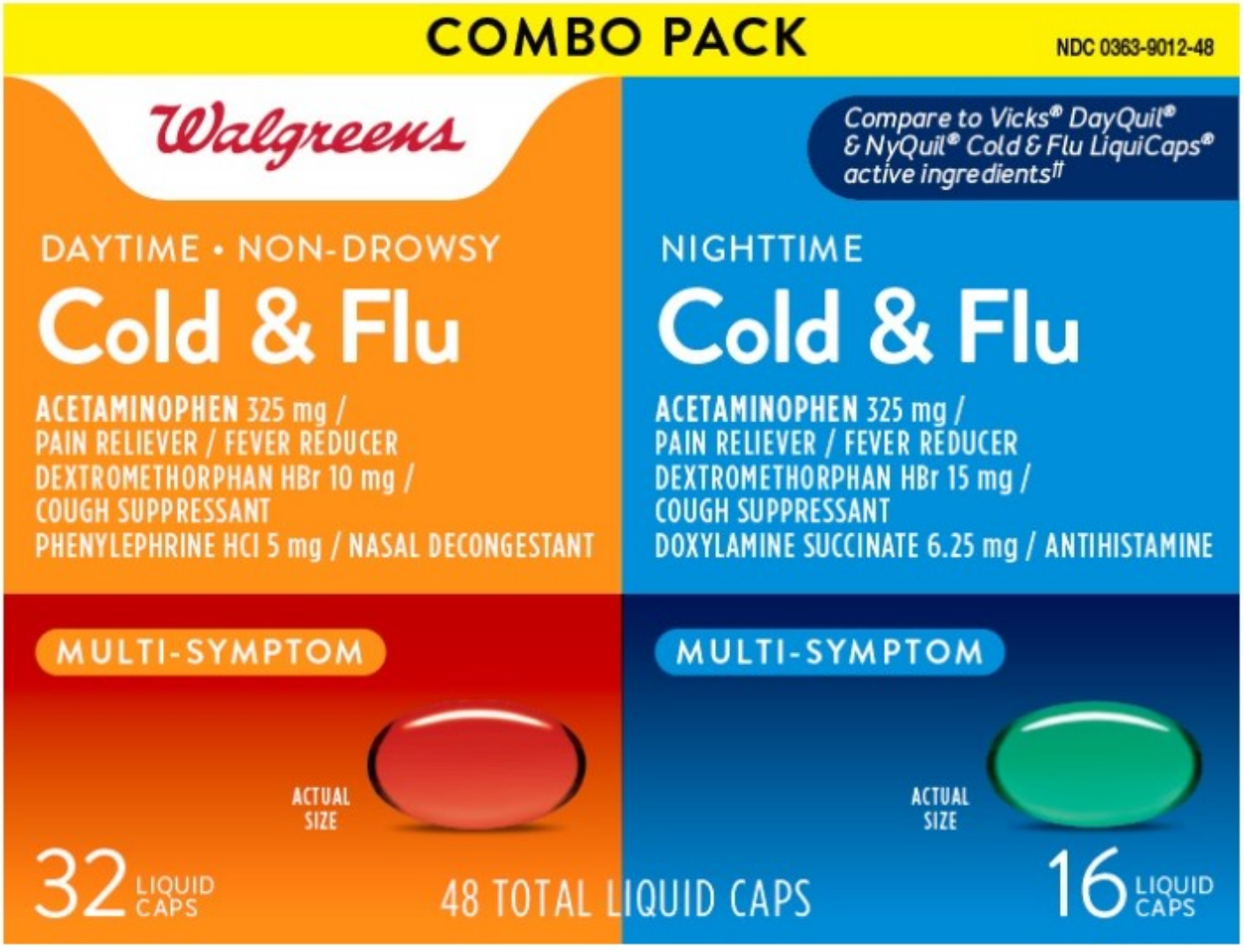
Inactive ingredients (Nighttime only)

D&C Yellow# 10, FD&C Blue# 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL



COLD AND FLU DAYTIME, NIGHTTIME, MULTI-SYMPTOM

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-9012

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0363-9012-48	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	08/24/2021	

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

DAYTIME COLD AND FLU DAYTIME, MULTI-SYMPTOM

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

Product Information	
Item Code (Source)	NDC:0363-9989
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	10 mg
PHENYLEPHRINE HYDROCHLORIDE (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 (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	red (Orange to Red)	**Score**	no score
Shape	OVAL (OBLONG)	**Size**	20mm
Flavor		**Imprint Code**	512;A09
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 Drug	M012	08/24/2021	

Part 2 of 2

NIGHTTIME COLD AND FLU NIGHTTIME, MULTI-SYMPTOM

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information	
Item Code (Source)	NDC:0363-9988
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)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	**Score**	no score
Shape	OVAL (OBLONG)	**Size**	20mm
Flavor		**Imprint Code**	215;902
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 Drug	M012	08/24/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/24/2021	

Labeler - Walgreens (008965063)

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