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

-----

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 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- 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

DAY & NIGHT PACK



# 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:0363-9011 Packaging # Item Code Package Description Marketing Start Date Marketing End Date

1 NDC:0363- 9011-24	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	08/24/2021	
------------------------	--	------------	--

Quant	Quantity of Parts			
Part #	Package Quantity	Total Product Quantity		
Part 1	2 BLISTER PACK	16		
Part 2	1 BLISTER PACK	8		

#### 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:0363-9987	
Route of Administration	ORAL	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients		
Ingredient Name	Strength	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)		
POVIDONE K30 (UNII: U725QW/32X)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SORBITOL (UNII: 506T60A25R)		
SORBITAN (UNII: 6092ICV9RU)		
WATER (UNII: 059QF0KO0R)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		

Product Characteristics			
Color	red (Orange to Red)	Score	no score
Shape	OVAL (OBLONG)	Size	20mm

Flavor	Imprint Code	512;A09
Contains		

Pa	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 Application Number or Monograph Category 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:0363-9986	
Route of Administration	ORAL	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (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: 6092ICV9RU)	

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			

P	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)

Revised: 12/2023 Walgreens