# COLD AND FLU DAYTIME NIGHTTIME- acetaminophen, dextromethorphan hbr, diphenhydramine hcl, guaifenesin, phenylephrine hcl WALMART INC.

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#### Equate 44-617694-09-Cold and Flu

#### Active ingredients (in each caplet) (Daytime Cold & Flu)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

#### Purpose (Daytime Cold & Flu))

Pain reliever/fever reducer Cough suppressant Expectorant Nasal decongestant

#### Active ingredients (in each caplet) (Nighttime Cold & Flu)

Acetaminophen 325 mg Diphenhydramine HCl 12.5 mg Phenylephrine HCl 5 mg

## Purpose (Nighttime Cold & Flu)

Pain reliever/fever reducer Antihistamine/cough suppressant Nasal decongestant

#### Uses

- temporarily relieves these common cold and flu symptoms:
  - headache
  - minor aches and pains
  - nasal congestion
  - cough
  - sore throat
  - sinus congestion and pressure
  - runny nose and sneezing (Nighttime only)
  - itching of the nose or throat (Nighttime only)
  - itchy, watery eyes due to hay fever (Nighttime only)
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (Daytime

#### only)

- controls cough to help you get to sleep
- temporarily reduces fever

#### 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:

- blisters
- rash
- skin reddening

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
- with any other product containing diphenhydramine, even one used on skin (Nighttime only)

## Ask a doctor before use if you have

- heart disease
- thyroid disease
- diabetes
- liver disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis (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)
- marked drowsiness may occur (Nighttime only)
- avoid alcoholic beverages (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
- pain, nasal congestion, 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.

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 for children even if you do not notice any signs or symptoms.

Do not take DAYTIME and NIGHTTIME products at the same time.

#### **Directions**

- do not take more than directed
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years and over: take 2 caplets every 4 hours
- children under 12 years: do not use

#### Other information

- each caplet contains: sodium 3 mg (Daytime only)
- 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)
- see end flap for expiration date and lot number

## Inactive ingredients (Daytime only)

corn starch, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

#### Inactive ingredients (Nighttime only)

corn starch, croscarmellose sodium, crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 aluminum lake, iron oxide yellow, magnesium stearate, methacrylic acid and ethyl acrylate copolymer, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium bicarbonate, stearic acid, talc, titanium dioxide

Questions or comments? 1-888-287-1915

# Principal display panel equate™

NDC 79903-236-20

Compare to
Maximum Strength
Mucinex® FAST-MAX®
Day Time Cold & Flu &
Night Time Cold & Flu
active ingredients\*

DAYTIME Cold & Flu NIGHTTIME Acetaminophen-Cold & Flu Pain Reliever/ Acetaminophen -Fever Reducer, Pain Reliever/ Dextromethorphan Fever Reducer, HBr -Diphenhydramine HCI Cough Suppressant Guaifenesin -Antihistamine/ Cough Suppressant Expectorant Phenylephrine HCl -Phenylephrine HCl -Nasal Decongestant Nasal Decongestant MAXIMUM MAXIMUM STRENGTH STRENGTH Relieves headache. • Relieves headache, body pain, sore body pain, sore throat. throat, fever, cough, itchy fever, cough, nasal & throat, chest congestion, nasal congestion, sinus congestion sneezing, runny nosel & pressure

12 Caplets
Caplets Actual Size
Actual Size

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

\*This product is not manufactured or distributed by RB Health (US) LLC, owner of the registered trademark Maximum Strength Mucinex® FAST-MAX® Day Time Cold & Flu and Night Time Cold & Flu. 50844 ORG082361769409

DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716

**PARENTS:** 

Learn about teen medicine abuse www.StopMedicineAbuse.org

Do not take **Daytime** and **Nighttime** caplets at the same time.

Satisfaction guaranteed Or we'll replace it or give you
your money back. For questions
or comments or to report an
undesired reaction or side effect,
please call **1-888-287-1915**.



Equate\_44-617694-09\_Cold\_and\_Flu

#### COLD AND FLU DAYTIME NIGHTTIME

acetaminophen, dextromethorphan hbr, diphenhydramine hcl, quaifenesin, phenylephrine hcl kit

# **Product Information HUMAN OTC DRUG Product Type** Item Code (Source) NDC:79903-236 **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79903-236- 20	1 in 1 CARTON; Type 0: Not a Combination Product	12/08/2023	

Quantity of Parts				
Part #	Package Quantity	Total Product Quantity		
Part 1	1 BLISTER PACK	12		
Part 2	1 BLISTER PACK	8		

## Part 1 of 2

# **COLD AND FLU DAYTIME**

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

Product Information			
Item Code (Source)	NDC:79903-235		
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		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients				
Ingredient Name	Strength			
STARCH, CORN (UNII: O8232NY3SJ)				
CROSPOVIDONE, UNSPECIFIED (UNII: 2S7830E561)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics			
Color	red	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	44;617
Contains			

ı	Packaging	ackaging			
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	<b>1</b> NDC:79903-235-10	12 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	OTC Monograph Drug	M012	12/08/2023	

# Part 2 of 2

# **COLD AND FLU NIGHTTIME**

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated

Product Information				
Item Code (Source)	NDC:79903-199			
Route of Administration	ORAL			

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg			
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg			
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg			

Inactive Ingredients			
Ingredient Name			
STARCH, CORN (UNII: 08232NY3SJ)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			

CROSPOVIDONE, UNSPECIFIED (UNII: 257830E561)

FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)

FD&C BLUE NO. 2 ALUMINUM LAKE (UNII: 4AQJ3LG584)

FERRIC OXIDE YELLOW (UNII: EX43802MRT)

MAGNESIUM STEARATE (UNII: 70097M6I30)

METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3MJQ0SDWLA)

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532859J990)

POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

SODIUM BICARBONATE (UNII: 8MDF5V39QO)

STEARIC ACID (UNII: 4ELV7Z65AP)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	44;694	
Contains				

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:79903-199- 10	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	12/08/2023	

Marketing In	Marketing Information				
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M012	12/08/2023			

## Labeler - WALMART INC. (051957769)

Establishment					
Name	Address	ID/FEI	Business Operations		
LNK International, Inc.		832867837	manufacture(79903-236) , pack(79903-236)		

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867894	manufacture(79903-236)	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
LNK International, Inc.		117025878	manufacture(79903-236)	

Revised: 12/2023 WALMART INC.