# DAYTIME NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride Walmart Inc.

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## Walmart Daytime & Nighttime cold & flu mini softgels

## Daytime Cold & Flu -Drug Facts

## Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

#### **Purposes**

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

#### Uses

- temporarily relieves these symptoms due to a cold or flu:
- minor aches and pains
- headache
- nasal congestion
- sore throat
- sinus congestion and pressure
- cough
- 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 or severe allergic reactions. Symptoms may include:

- skin reddening
- blisters
- rash
- hives
- facial swelling

- asthma (wheezing)
- shock

If a skin or general allergic 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
- in children under 12 years of age

#### Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- cough with excessive phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such 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 exceed recommended dosage

## Stop use and ask a doctor if

- pain, cough, or nasal congestion 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.
- nervousness, dizziness, or sleeplessness occurs

**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 (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### **Directions**

do not take more than the recommended dose

- do not take the Day and Night products at the same time; wait 4 hours after the last Night dose before starting Day product.
- adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 6 softgels with water every 4 hours. Do not exceed 6 softgels in 12 hours or as directed by a doctor.
- children under 12 years: do not use

#### Other information

store at no greater than 25°C

**Inactive ingredients**FD&C yellow no. 6 al. lake, gelatin, glycerin, mica, polyethylene glycol 400, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Questions or comments?Call 1-888-287-1915

# Nighttime Severe Cold & flu - Drug Facts Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan hydrobromide 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine hydrochloride 5 mg

## **Purposes**

Pain reliever/fever reducer

Cough suppressant

**Antihistamine** 

Nasal decongestant

#### Uses

- temporarily relieves these symptoms due to a cold or flu:
- minor aches and pains
- headache
- nasal congestion
- cough
- sinus congestion and pressure
- runny nose
- sneezing
- sore throat
- 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 or severe allergic reactions. Symptoms may include:

- skin reddening
- blisters
- rash
- hives
- facial swelling
- asthma (wheezing)
- shock

If a skin or general allergic 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 to sedate children.

#### 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
- in children under 12 years of age

## Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

## Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

## When using this product

do not exceed recommended dosage

- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

#### Stop use and ask a doctor if

- pain, cough, or nasal congestion 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.
- nervousness, dizziness, or sleeplessness occurs

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 (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### **Directions**

- do not take more than the recommended dose
- do not take the Day and Night products at the same time; wait 4 hours after the last Day dose before starting Night product.
- adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 4 softgels in 12 hours or as directed by a doctor.
- children under 12 years: do not use

#### Other information

store at no greater than 25°C

**Inactive ingredients**D&C yellow no. 10 al. lake, FD&C blue no.1 al. lake, gelatin, glycerin, mica, polyethylene glycol 400, povidone, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Questions or comments? Call 1-888-287-1915



#### DAYTIME NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

nyarochionae kit				
<b>Product Infor</b>	mation			
<b>Product Type</b>	HUMAN OTC DRUG	Item Code	(Source)	NDC:79903-383
Packaging				
# Item Code	Package Descri	ption	Marketing Start Date	Marketing End Date

1	NDC:79903-383- 16	2 in 1 CARTON	07/15/2025	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Quantity of Parts			
Part #	Package Quantity	Total Product Quantity	
Part 1	2 BLISTER PACK	12 in 2	
Part 2	2 BLISTER PACK	4 in 2	

## Part 1 of 2

## **DAYTIME COLD AND FLU**

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule

Product Information		
Item Code (Source)	NDC:79903-384	
Route of Administration	ORAL	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	

Inactive Ingredients	
Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN (UNII: 6092ICV9RU)	
MICA (UNII: V8A1AW0880)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B710)	
GELATIN (UNII: 2G86QN327L)	
POVIDONE (UNII: FZ 989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

<b>Product Characte</b>	eristics		
Color	orange	Score	no score

Shape	OVAL	Size	16mm
Flavor		Imprint Code	151
Contains			

Packaging				
#	Item Package Description		Marketing Start Date	Marketing End Date
1		6 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	07/15/2025	

## Part 2 of 2

## **NIGHTTIME COLD AND FLU**

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl capsule

Product Information		
Item Code (Source)	NDC:79903-385	
Route of Administration	ORAL	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg

Inactive Ingredients			
Ingredient Name	Strength		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)			
GELATIN (UNII: 2G86QN327L)			
POVIDONE (UNII: FZ 989GH94E)			
WATER (UNII: 059QF0KO0R)			
SHELLAC (UNII: 46N107B710)			

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

SORBITAN (UNII: 6092ICV9RU)

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

GLYCERIN (UNII: PDC6A3C0OX)

MICA (UNII: V8A1AW0880)

Product Characteristics			
Color	green	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	163
Contains			

l	Packaging				
	# Item Package Description		Marketing Start Date	Marketing End Date	
	1		2 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	07/15/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/15/2025	

# Labeler - Walmart Inc. (051957769)

# **Registrant -** TIME CAP LABORATORIES, INC. (037052099)

Establishment			
Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(79903-383, 79903-384, 79903-385)

Revised: 5/2025 Walmart Inc.