**DAYTIME NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate and phenylephrine hcl liquid filled capsules**
**Walmart Inc.**

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**634T_Daytime Nighttime Severe Cold and Flu Softgels**

## *Drug Facts - Daytime Cold & Flu*

Active ingredients (in each softgel)

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
cough
sore throat
nasal congestion
sinus congestion and pressure

- 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 (1-800-222-1222) right away. 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 in 12 hours or as directed by a doctor.
- children under 12 years: do not use

### *Other information*

store at room temperature
avoid temperature above 25°C (77°F)

***Inactive ingredients*** FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

### *Questions or Comments?*

Call **1-877-290-4008**

### *Drug Facts - Nighttime Cold & Flu*

### *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
cough
nasal congestion
runny nose
sneezing
sore throat
sinus congestion and pressure

- 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 (1-800-222-1222) right away. 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

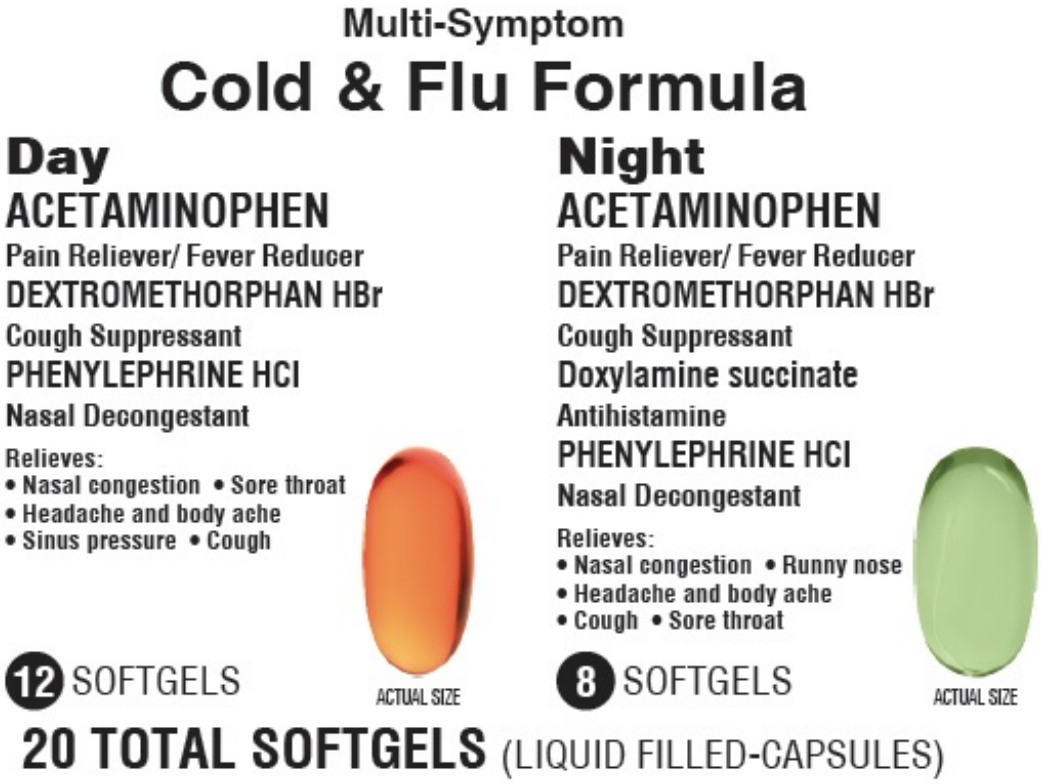
***Other information***

- store at room temperature
- avoid temperature above 25°C (77°F)

***Inactive ingredients*** FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

***Questions or Comments?***

Call **1-877-290-4008**




# DAYTIME NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate and phenylephrine hcl liquid filled capsules kit

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:79903-315 |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:79903-315-20 | 1 in 1 CARTON | 03/01/2025 | |

| Quantity of Parts | | |
|---|---|---|
| **Part #** | **Package Quantity** | **Total Product Quantity** |
| **Part 1** | 12 BLISTER PACK | 12 in 2 |
| **Part 2** | 8 BLISTER PACK | 8 in 2 |

## Part 1 of 2

## DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule, liquid filled

## Product Information

| | |
|---|---|
| **Item Code (Source)** | NDC:79903-320 |
| **Route of Administration** | ORAL |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **SORBITOL SOLUTION** (UNII: 8KW3E207O2) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **SHELLAC** (UNII: 46N107B71O) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | orange | **Score** | no score |
| **Shape** | OVAL (Oblong shaped capsules) | **Size** | 16mm |
| **Flavor** | | **Imprint Code** | 70 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 1 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 | 03/01/2025 | |

## Part 2 of 2

# NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride liquid filled capsules capsule, liquid filled

### Product Information

| | |
|---|---|
| **Item Code (Source)** | NDC:79903-321 |
| **Route of Administration** | ORAL |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 mg |
| **ACETAMINOPHEN** (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| **DOXYLAMINE SUCCINATE** (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 6.25 mg |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 5 mg |

### Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **GELATIN** (UNII: 2G86QN327L) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **POVIDONE** (UNII: FZ989GH94E) | |
| **SHELLAC** (UNII: 46N107B71O) | |
| **SORBITOL SOLUTION** (UNII: 8KW3E207O2) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WQ0SDW1A) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

### Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | green | **Score** | no score |
| **Shape** | OVAL (oblong shaped capsules) | **Size** | 16mm |
| **Flavor** | | **Imprint Code** | 72 |
| **Contains** | | | |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | | 1 in 1 BLISTER PACK; Type 0: Not a Combination | | |

| | | | | |
|---|---|---|---|---|
| 1 | | Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M012 | 03/01/2025 | |


## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M012 | 03/01/2025 | |


## Labeler - Walmart Inc. (051957769)

## Registrant - TIME CAP LABORATORIES INC (037052099)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| MARKSANS PHARMA LTD | | 925822975 | manufacture(79903-315) |

Revised: 11/2024 Walmart Inc.