

**DAYTIME NIGHTTIME COLD FLU RELIEF- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl**  
**EQUATE (Wal-Mart Stores, Inc.)**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**DRUG FACTS**

**Active ingredients for Daytime (in each softgel)**

**Acetaminophen 325 mg**

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

**Active ingredients for Nighttime (in each softgel)**

**Acetaminophen 325 mg**

Dextromethorphan HBr 15 mg

Doxylamine succinate 6.25 mg

**Purpose for Daytime**

**Pain reliever/fever reducer**

Cough suppressant

Nasal decongestant

**Purpose for Nighttime**

**Pain reliever/fever reducer**

Cough suppressant

Antihistamine

**Uses**

**DAYTIME**

- temporarily relieves common cold and flu symptoms
  - cough due to minor throat and bronchial irritation
  - nasal congestion
  - headache
  - minor aches and pains
  - fever
  - sore throat

**NIGHTTIME**

- temporarily relieves common cold and flu symptoms
  - cough due to minor throat and bronchial irritation
  - sore throat

- headache
- minor aches and pains
- fever
- runny nose and sneezing

## Warnings

### DAYTIME

**Liver warning:** These products contain 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 these products

**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.

### NIGHTTIME

**Liver warning:** This product contain 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 following by fever, headache, rash, nausea, vomiting, consult a doctor promptly.

## Do not use

### DAYTIME

- 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.

### NIGHTTIME

- 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.

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

#### DAYTIME

- liver disease
- heart disease
- diabetes
- thyroid disease
- high blood pressure
- cough that occurs with too much phlegm (mucus)
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

#### NIGHTTIME

- liver disease
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to an enlarged prostate gland

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

#### DAYTIME

taking the blood thinning drug warfarin

#### NIGHTTIME

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

### **When using this product,**

#### DAYTIME

**do not exceed recommended dosage**

#### NIGHTTIME

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

### **Stop use and ask a doctor if**

#### DAYTIME

- nervousness, dizziness or sleeplessness occur
- pain, cough, and nasal congestion gets worse or lasts more than 7 days
- redness or swelling is present
- new symptoms occur
- fever gets worse or lasts more than 3 days
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

#### **NIGHTTIME**

- pain 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 headache that lasts.

These could be a signs of a serious condition.

#### **If pregnant or breast-feeding,**

ask a health professional before use.

#### **Keep out of reach of children.**

**Overdose warning:** Taking more than the recommended dose can cause liver damage. 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**

##### **DAYTIME**

- **do not take more than directed (see Overdose warning)**
- do not take more than 4 doses in 24 hours
- swallow whole; do not crush, chew, or dissolve
- adults and children 12 years and over; take 2 softgels with water every 4 hours.
- children under 12 years: do not use

##### **NIGHTTIME**

- **do not take more than directed (see Overdose warning)**
- do not take more than 4 doses in 24 hours
- swallow whole; do not crush, chew, or dissolve
- adults and children 12 years and over: take 2 softgels with water every 6 hours
- children under 12 years: do not use

#### **Other information**

- store between 15-30°C (59-86°F)
- avoid excessive heat

#### **Inactive ingredients**

##### **DAYTIME**

butylated hydroxyanisole, butylated hydroxytoluene, FD&C yellow #6, gelatin, glycerin, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

##### **NIGHTTIME**

D&C yellow #10, FD&C blue #1, gelatin, glycerin, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, white ink

## Questions or comments?

Call 1-888-287-1915

### Principal Display Panel

Compare to the active ingredients in Vicks® DayQuil® and NyQuil® Cold & Flu LiquiCaps®

#### DAYTIME

Multi-Symptom

Cold & Flu Relief

Acetaminophen 325 mg- Pain reliever / Fever reducer

Dextromethorphan HBr 10 mg - Cough suppressant

Phenylephrine HCl 5 mg - Nasal decongestant

Relieves

- Aches, fever, sore throat
- Cough
- Nasal congestion

Non-drowsy

Alcohol-Free

Antihistamine-Free

Softgels\*\*

(\*\* Liquid-filled capsules)

#### NIGHTTIME

Multi-Symptom

Cold & Flu Relief

Acetaminophen 325 mg - Pain reliever / Fever reducer

Dextromethorphan HBr 15 mg - Cough suppressant

Doxylamine succinate 6.25 mg - Antihistamine

Relieves

- Aches, fever, sore throat
- Cough
- Runny nose, sneezing

Alcohol-free

Softgels\*\*

(\*\*Liquid-filled capsules)

When using Daytime and Nighttime products, carefully read the labeling to ensure correct dosing.

†This product is not manufactured or distributed by The Procter & Gamble Company. Vicks®, DayQuil, NyQuil®, and LiquiCaps® are registered trademarks of the Procter and Gamble Company.

**TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOW SIGNS OF TAMPERING.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

Distributed by:

Walmart Inc.,

Bentonville, AR 72716

**Product Label**



# DAYTIME NIGHTTIME COLD FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-192
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-192-48	1 in 1 KIT; Type 0: Not a Combination Product	01/30/2020	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	16 BLISTER PACK	16
Part 2	32 BLISTER PACK	32

## Part 1 of 2

### NIGHTTIME COLD FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule

## Product Information

Route of Administration	ORAL
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## 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: HBR47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	



<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	

### Product Characteristics

<b>Color</b>	GREEN	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	PC10
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		16 in 1 CARTON		
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 FINAL	part341	01/30/2020	

## Part 2 of 2

### DAYTIME COLD FLU RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule

### Product Information

<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>BUTYLATED HYDROXYANISOLE</b> (UNII: REK4960K2U)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	

### Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	PC9
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		32 in 1 CARTON		
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 FINAL	part341	01/30/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	01/30/2020	

**Labeler** - EQUATE (Wal-Mart Stores, Inc.) (051957769)

Revised: 11/2019

EQUATE (Wal-Mart Stores, Inc.)