# DAYTIME NIGHTTIME COLD AND FLU- acetaminophen dextromethorphan hbr phenylephrine hci doxylaminesucinate Harris Teeter, LLC

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 (in each 15 mL) DAYTIME

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg

## Active ingredients for (in each 30 mL) NIGHTTIME

Acetaminophen 650 mg
Dextromethorphan HBr 30 mg
Doxylamine Succinate 12.5 mg

# **Purposes for Day Time**

Pain reliever/fever reducer Cough suppressant Nasal decongestant

# **Purpose for Night Time**

Pain reliever/fever reducer
Cough suppressant
Antihistamine

#### Uses

#### **DAYTIME**

- temporarily relieves common cold and flu symptoms
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion

- fever
- cough due to minor throat and bronchial irritation

#### **NIGHTTIME**

- temporarily relieves these common cold/flu symptoms`
  - minor aches and pains
  - headache
  - sore throat
  - runny nose and sneezing
  - fever
  - cough due to minor throat and bronchial irritation

#### **Warnings**

#### **DAYTIME**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 4 doses (30 mL each) of acetaminophen in 24 hours, which is the maximum daily amount
- child takes more than 4 doses (15 mL each) in 24 hours
- taken with other drugs containing acetaminophen
- adult has 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.

#### **NIGHTTIME**

**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

#### **DAYTIME 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 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

# Ask a doctor before use if you have

#### **DAYTIME**

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

#### **NIGHTTIME**

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

# Ask a doctor or pharmacist before use if you are

#### **DAYTIME**

taking the blood thinning drug warfarin.

#### **NIGHTTIME**

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

# When using this product

#### **DAYTIME**

do not exceed recommended dosage.

#### **NIGHTTIME**

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

#### Stop use and ask a doctor if

#### **DAYTIME**

- nervousness, dizziness or sleeplessness occur
- pain, nasal congestion, or cough gets worse, or lasts more than 5 days(children) or 7 days (adult)
- 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.

#### **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, 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.

#### **DAYTIME NIGHTTIME**

Taking more than the recommended dose (overdose) may 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 any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- keep dosing cup with product
- mL= milliliter

children 6 to under 12 years	15 mL every 4 hours
children 4 to under 6 years	ask a doctor
children under 4 years	do not use

#### **NIGHTTIME**

- do not take more than directed (see Overdose warning)
- Do not take more than 4 doses in any 24-hours period
- measure only with dosing cup provided. Do not use any other dosing device.
- mL= milliliter
- keep dosing cup with product
- adults and children 12 years and over: 30 mL every 6 hours
- children under 12 years of age: do not use
- when using other Daytime or Nighttime products, carefully read each label or ensure correct dosing

#### Other information

#### DAYTIME

- each 15 mL contains: sodium 12 mg
- store between 20-25°C (68-77°). Do not refrigerate

#### NIGHTTIME

- each 30 mL contains: potassium 5 mg
- each 30 mL contains sodium 24 mg
- store between 20-25°C (68-77°F). Do not refrigerate

# **Inactive ingredients**

# **Day Time**

citric acid, FD&C yellow #6, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, sodium citrate, sorbitol, sucralose, xanthan gum

# **Night Time**

acesulfume potassium, alcohol, anhydrous citric acid, FD&C blue #1, Fd&C red #40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium trisodium citrate dihydrate

#### Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-4PM MST

#### **Principal Display Panel**

\*Compare to the active ingredients in Vicks® DayQuil® Cold & Flu

**DayTime** 

ACETAMINOPHEN 325 mg

Pain Reliever/Fever Reducer

DEXTROMETHORPHAN HBr 10 mg • Cough Suppressant

PHENYLEPHRINE HCI 5mg • Nasal Decongestant

#### **COLD & FLU**

Daytime Relief

- Aches, Fever, & Sore Throat
- Cough
- Nasal Congestion

#### FOR AGES 6 YEARS AND OVER

**ALCOHOL-FREE** 

#### **ANTIHISTAMINE-FREE**

#### **NON-DROWSY**

\*Compare to the active ingredients in Vicks® Nyquil® Cold & Flu

NightTime

ACETAMINOPHEN 650 mg

Pain Reliever/Fever Reducer,

DEXTROMETHORPHAN HBr 30 mg • Cough Suppressant,

DOXYLAMINE SUCCINATE 12.5 mg • Antihistamine

#### **COLD & FLU**

Nighttime Relief

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Sneezing, Runny Nose
- Cough

Cherry Flavor

#### **FOR AGES 12 YEARS AND OVER**

#### **ALCOHOL 10%**

FL OZ (mL)

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WHEN USING OTHER DAYTIME OR NIGHTTIME PRODUCTS, CAREFULLY READ

#### EACH LABEL TO ENSURE CORRECT DOSING.

# TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND DOSAGE CUP OR UNDER CAP IS BROKEN OR MISSING.

PROUDLY DISTRIBUTED BY:

HARRIS TEETER, LLC

MATTHEWS, NC 28105

#### **Product Label**



HARRIS TEETER DayTime Cold & Flu NightTime Cold & Flu Cherry Flavor

#### **DAYTIME NIGHTTIME COLD AND FLU**

acetaminophen dextromethorphan hbr phenylephrine hci doxylaminesucinate kit

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69256-467	

ı	Pa	ckaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:69256-467- 24	1 in 1 KIT; Type 0: Not a Combination Product	05/28/2021	

Quantity of Parts			
Part #	Package Quantity	Total Product Quantity	
Part 1	1 BOTTLE	355 mL	
Part 2	1 BOTTLE	355 mL	

# Part 1 of 2

# **DAYTIME COLD AND FLU NON DROWSY**

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

## **Product Information**

Item Code (Source) NDC:69256-466

**Route of Administration** ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg in 15 mL		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 15 mL		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 15 mL		

Inactive Ingredients			
Ingredient Name	Strength		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)			
GLYCERIN (UNII: PDC6A3C0OX)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
SORBITOL (UNII: 506T60A25R)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
XANTHAN GUM (UNII: TTV12P4NEE)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		355 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Application Number or Monograph Marketing Start Mar Category Citation Date				
OTC monograph final	part341	05/28/2021		

# Part 2 of 2

# **NIGHTTIME COLD AND FLU**

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate liquid

# **Product Information**

Item Code (Source) NDC:69256-343

**Route of Administration** ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL		
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL		

Inactive Ingredients	
Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				

Pa	ackaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
		355 mL in 1 BOTTLE; 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	05/28/2021	
Mayleating Ind	.formation		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/28/2021	

# Labeler - Harris Teeter, LLC (048463103)

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