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

-----

## **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

adults and children 12 years and over	30 mL every 4 hours
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  ${\bf @}$  DayQuil  ${\bf @}$  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)

\*This product is not manufactured or distributed by THE PROCTER & GAMBLE COMPANY. VICKS® DayQuil® and NyQuil® are registered trademarks of THE PROCTER & GAMBLE COMPANY.

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:

#### **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**

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

Packaging					
4	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69256-467-	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 Package Description Marketing Start Marketing End Date Date				Marketing End Date
1		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 Drug	M012	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			

ı	Packaging				
# Item Package Description Marketing Sta				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 Citation	Marketing Start	Marketing End	
Category		Date	Date	

OTC Monograph Drug	M012	05/28/2021			
Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M012	05/28/2021			

## Labeler - Harris Teeter, LLC (048463103)

Revised: 4/2024 Harris Teeter, LLC