

**DAYTIME NIGHTTIME SEVERE COLD AND FLU- acetaminophen
dextromethorphan hbr guaifenesin phenylephrine hcl doxylaminesuccinate
Family Dollar (FAMILY WELLNESS)**

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.

Drug Facts

Active ingredients (in each 15 mL) DAYTIME

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Active ingredients for (in each 30 mL) NIGHTTIME

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Doxylamine Succinate 12.5 mg

Phenylephrine HCL 10 mg

Purposes for Day Time

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Purpose for Night Time

Pain reliever/fever reducer

Cough suppressant

Antihistamine

Nasal decongestant

Uses

DAYTIME

- temporarily relieves common cold and flu symptoms
 - nasal congestion
 - sinus congestion and pressure
 - minor aches and pain
 - headache
 - fever
 - sore throat
 - reduces swelling of nasal passages
 - cough due to minor throat and bronchial irritation
 - temporarily restores freer breathing through the nose
 - promotes nasal and/or sinus drainage
- help loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make cough more productive

NIGHTTIME

- temporarily relieves these common cold/flu symptoms`
 - nasal congestion
 - sore throat
 - headache
 - sinus congestion and pressure
 - minor aches and pains
 - runny nose and sneezing
 - cough due to minor throat and bronchial irritation
- temporarily reduces
 - fever
 - cough to help you sleep
 - swelling of nasal passage
 - temporarily restores freer breathing through the nose
 - promotes nasal and/or sinus drainage

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
- heart disease
- high blood pressure

- thyroid disease
- diabetes
- 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
- a sodium-restricted diet

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 take more than directed.

NIGHTTIME

- **do not take more than directed**
- 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

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, 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

- **take only as directed (see Overdose warning)**
- Do not exceed 4 doses per 24 hours
- 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 4 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°F). Do not refrigerate

NIGHTTIME

- **each 30 mL contains:** sodium 64 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

anhydrous citric acid, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium chloride, trisodium citrate dihydrate, sorbitol, sucralose, xanthan gum

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

COMPARE TO THE ACTIVE INGREDIENTS IN VICKS® DAYQUIL® AND NYQUIL® SEVERE COLD & FLU*

SEVERE Cold & Flu Relief

DAYTIME

Acetaminophen (Pain Reliever / Fever Reducer)

Dextromethorphan HBr (Cough Suppressant)

Guaifenesin (Expectorant)

Phenylephrine HCl (Nasal Decongestant)

Relieves

- Headache, Fever, Sore Throat, Minor Aches & Pains
- Nasal/Sinus Congestion & Sinus Pressure
- Cough
- Chest Congestion

For ages 6 years and over

Max Strength

Non-Drowsy

Alcohol Free

When using other Daytime or Nighttime products, carefully read each label to ensure correct dosing

NIGHT TIME

Acetaminophen (Pain Reliever / Fever Reducer)

Dextromethorphan HBr (Cough Suppressant)

Doxylamine Succinate (Antihistamine)

Phenylephrine HCL (Nasal Decongestant)

Relieves

- Headache, Fever, Sore Throat, Minor Aches & Pain
- Nasal/Sinus Congestion & Sinus Pressure
- Sneezing
- Runny Nose
- Cough

Max Strength

Alcohol Free

FL OZ (mL)

BERRY FLAVOR

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

DISTRIBUTED BY

MIDWOOD BRANDS, LLC

500 VOLVO PARKWAY

CHESAPEAKE, VA 23320

Product Label



FAMILY WELLNESS DayTime Nighttime Severe Cold and Flu Relief

DAYTIME NIGHTTIME SEVERE COLD AND FLU				
acetaminophen dextromethorphan hbr guaifenesin phenylephrine hcl doxylaminesucinate kit				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-813	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-813-16	1 in 1 KIT; Type 0: Not a Combination Product	07/31/2019	07/31/2025
Quantity of Parts				
Part #	Package Quantity	Total Product Quantity		
Part 1	1 BOTTLE	237 mL		
Part 2	1 BOTTLE	237 mL		
Part 1 of 2				
DAYTIME SEVERE COLD AND FLU				
acetaminophen dextromethorphan hbr guaifenesin phenylephrine hcl liquid				
Product Information				
Route of Administration	ORAL			

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 15 mL
DEXTROMETHORPHAN HYDROBROMIDE (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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 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		237 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	07/31/2019	

Part 2 of 2**NIGHTTIME SEVERE COLD AND FLU**

acetaminophen dextromethorphan hbr doxylamine succinate phenylephrine hcl liquid

Product Information**Route of Administration** ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 30 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		237 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	07/31/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/31/2019	07/31/2025

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 1/2023

Family Dollar (FAMILY WELLNESS)