DAYTIME NIGHTTIME SEVERE COLD AND FLU RELIEF- acetaminophen dextromethorphan hbr guaifenesin phenylephrine hci doxylamine sucinate Family Dollar (FAMILY WELLNESS)

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 HCI 10 mg

Purposes for DayTime

Pain reliever/fever reducer Cough suppressant Expectorant Nasal decongestant

Purpose for NightTime

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 pains
- 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 coughs 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 passages
 - 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.

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 the user has

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
- thyroid disease
- high blood pressure
- diabetes
- glaucoma

- a sodium-restricted diet
- 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 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 or 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

Overdose warning:Taking more than the recommended dose (overdose) may couse 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

- take only as 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°). Do not refrigerate

NIGHTTIME

- each 30 mL contains: sodium 64 mg
- store between 20-25°C (68-77°F). Do not refrigerate

Inactive ingredients

DayTime

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

NightTime

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 dehydrate, 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 of Vicks ® DayQuil® and NyQuil® Severe Cold & Flu*

DAYTIME

DAYTIME

COLD & FLU RELIEF

ACETAMINOPHEN 325 mg

Pain reliever / Fever reducer

Dextromethorphan HBr 10 mg

Cough suppressant

Guaifenesin 200 mg

Expectorant

Phenylephrine HCI 5 mg

Nasal decongestant

Relieves

- Headache, fever, sore throat, minor aches & pains
- Nasal/sinus congestion & sinus pressure
- Cough
- Chest congestion

Max strength

Alcohol free

Non-drowsy

NIGHTTIME

NIGHTTIME

COLD & FLU RELIEF

ACETAMINOPHEN 650 mg

Pain reliever / Fever reducer

Dextromethorphan HBr 20 mg

Cough suppressant

Doxylamine succinate 12.5 mg

Antihistamine

Phenylephrine HCI 10 mg

Nasal decongestant

Relieves

- Headache, fever, sore throat, minor aches & pains
- Nasal/sinus congestion & sinus pressure
- Sneezing
- Runny nose
- Cough

Max strength

Alcohol free

FL OZ (mL)

BERRY FLAVOR

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

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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 PKWY, CHESAPEAKE, VA 23320

Product Label



FAMILY WELLNESS Daytime Nighttime Cold & Flu Relief

DAYTIME NIGHTTIME SEVERE COLD AND FLU RELIEF

acetaminophen dextromethorphan hbr guaifenesin phenylephrine hci doxylamine sucinate kit

			Product Information				
Produc	t Type	HUMAN	OTC DRUG	Item Co	ode (Source)	NDC:55319-138	
Packa	ging						
# Iter	m Code	Pac	kage Descriptio	ו	Marketing Start Date	Marketing End Date	
1 NDC:5	5319-138-	1 in 1 KIT; Ty Product	pe 0: Not a Combinat	ion	07/31/2024		
Quant	ity of Pa	rts					
Part #		Package Q	uantity		Total Product	Quantity	
	1 BOTTLE, F			237 mL			
Part 2 1 BOTTLE, PLASTIC		237 mL					
Part	1 of 2						
		VFRF C					
DAYT			OLD AND FLU	J REL	IEF		
DAYT				J REL			
DAYT				J REL	IEF		
DAYT acetam		lextrometho		J REL	IEF		
DAYT acetam Produc	TIME SE	lextrometho nation		J REL	IEF		
DAYT acetam Produc	rime se inophen c ct Inform	dextrometho nation ce)	orphan hbr guaifer	J REL	IEF		
DAYT acetam Produc	rime se ninophen c ct Inform ode (Sourc	dextrometho nation ce)	NDC:55319-145	J REL	IEF		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
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
	NDC:55319- 145-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M012	07/31/2024	

Part 2 of 2

SEVERE NIGHTTIME COLD AND FLU RELIEF

acetaminophen dextromethorphan hbr doxylamine succinate phenylephrine hci liquid

Product Information

Item Code (Source) NDC:55319-641

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 30 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 30 mL	
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (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	

Strength

Product Characteristic	CS		
Color		Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

P	ackaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319- 641-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
N	larketing	Information		
M	larketing	Information		

OTC Monograph Drug	M012

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	07/31/2024		

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 8/2024

Family Dollar (FAMILY WELLNESS)