## DAYTIME NIGHTTIME COLD AND FLU RELIEF MULTI-SYMPTOMacetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl

## 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.

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### **Drug Facts**

## Active ingredients in Daytime (in each softgel)

## Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

## Active ingredients in 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 fly symptoms
  - o cough due to minor throat and bronchial irritation
  - sore throat
  - headache
  - minor aches and pain
  - fever
  - runny nose and sneezing

## Warnings

#### **DAYTIME and NIGHTTIME**

**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 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 and 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 that lasts such as occur 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**

- excitability may occur, especially in children
- avoid alcoholic drinks
- marked drowsiness may occur
- 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
- 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 and NIGHTTIME**

**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 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 disolve
- adults and children 12 years and over: take 2 softgels with water every 6 hours
- children under 12 years: do not use

#### Other information

#### **DAYTIME and NIGHTTIME**

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

## **Inactive ingredients**

**Daytime** butylated hydroxyanisole, butylated hydroxytoluene, FD&C red #40\*, FD&C yellow #6\*, gelatin, glycerin, polyethylene glycol\*, povidone, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide\*, white ink

\*may contain this ingredient

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

titanium dioxide\*

\*may contain this ingredient

#### 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® LIQUICAPS®\*\*

Multi-Symptom

Cold & Flu Relief

## **Acetaminophen - Pain Reliever / Fever Reducer**

Dextromethorphan HBr - Cough Suppressant

Phenylephrine HCl - Nasal Decongestant

**SOFTGELS** 

#### **NIGHTTIME**

Acetaminophen - Pain Reliever / Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Doxylamine Succinate - Antihistamine

**SOFTGELS** 

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

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

# KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY: MIDWOOD BRANDS, LLC 10611 MONROE RD., MATTHEWS, NC 28105

#### **Product Label**



FAMILY WELLNESS DayTime NightTime Cold & Flu Relief

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55319-744

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55319-744- 24	1 in 1 KIT; Type 0: Not a Combination Product	04/30/2018	07/26/2024	

Quant	Quantity of Parts				
Part #	Package Quantity	Total Product Quantity			
Part 1	8 BLISTER PACK	8			
Part 2	16 BLISTER PACK	16			

## Part 1 of 2

## **NIGHTTIME COLD AND FLU**

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule

#### **Product Information**

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (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: H3R47K3TBD)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE (UNII: FZ989GH94E)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				

SORBITAN (UNII: 6O92ICV9RU)
SORBITOL (UNII: 506T60A25R)

Product Characteristics					
Color	green	Score	no score		
Shape	CAPSULE	Size	20mm		
Flavor		Imprint Code	P30;94A;P120;AP017		
Contains					

Pa	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1		8 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	04/30/2018	07/26/2024		

## Part 2 of 2

## **DAYTIME COLD AND FLU**

acetaminophen, dextromethorphan hbr, phenylephrine hci capsule

#### **Product Information**

Route of Administration ORAL

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

Inactive Ingredients	
Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6092ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics					
Color	orange	Score	no score		
Shape	CAPSULE	Size	20mm		
Flavor		Imprint Code	P19;95A;512;AP016		
Contains					

Pa	Packaging					
#	# Item 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	04/30/2018	07/26/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/30/2018	07/26/2024

## Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 9/2022 Family Dollar (FAMILY WELLNESS)