DAYTIME NIGHTTIME COLD FLU RELIEF- acetaminophen, 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.

DRUG FACTS

Active ingredients for Daytime (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Active ingredients for 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
 - o cough due to minor throat and bronchial irritation
 - nasal congestion
 - headache
 - minor aches and pains
 - fever
 - sore throat

NIGHTTIME

- temporarily relieves common cold and flu symptoms
 - cough due to minor throat and bronchial irritation
 - sore throat

- headache
- minor aches and pains
- fever
- runny nose and sneezing

Warnings

DAYTIME

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 these products

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 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

Alergy 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 following by fever, headache, rash, nausea, vomiting, consult a doctor promptly.

Do not use

DAYTIME

- 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.

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
- diabetetes
- 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 such as occurs 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 use more than directed

NIGHTTIME

- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks
- 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
- redness or swelling is present
- new symptoms occur
- fever gets worse or lasts more than 3 days
- 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 headache that lasts.

These could be a signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Other information

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

Inactive ingredients

DAYTIME

butylated hydroxyanisole, butylated hydroxytoluene, carminic acid*, D&C yellow #10*, edible white ink, FD&C red #40*, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sodium metabisulfite*, sorbitan*, sorbitol, *contain one or more of these ingredient

NIGHTTIME

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

Questions or comments?

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

Principal Display Panel

DAYTIME

MULTI-SYMPTOM

Cold & Flu Relief

DayTime / Non-Drowsy

Acetaminophen Pain Reliever/Fever Reducer

Dextromethorphan HBr Cough Suppressant

Phenylephrine HCI Nasal Decongestant

SOFTGELS

NIGHTTIME

Acetaminophen Pain Reliever/Fever Reducer

Dextromethorphan HBr Cough Suppressant

Doxylamine succinate Antihistamine

SOFTGELS

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

DISTRIBUTED BY: MIDWOOD BRANDS,, llc

10611 MONROE RD, MATTHEWS, NC 28105 USA

Product Label



FAMILY WELLNESS DayTime NightTime Multi-symptom Cold & Flu

DAYTIME NIGHTTIME COLD FLU RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55319-472

Packaging

I	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:55319-472-24	1 in 1 CARTON; Type 0: Not a Combination Product	03/31/2016	

Quantity of Parts

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

Part 1 of 2

NIGHTTIME COLD FLU RELIEF

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength ACETAMINOPHEN (UNII: 36209 ITL9 D) (ACETAMINOPHEN - UNII:36209 ITL9 D) DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RT19 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) DOXYLAMINE SUCCINATE (UNII: V9 B19 B5YI2) (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)	
PO VIDO NE (UNII: FZ989 GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Charact	Product Characteristics			
Color GREEN		Score	no score	
Shape	CAPSULE	Size	21mm	
Flavor		Imprint Code	P30;94A;SCU1;215;P120	
Contains				

Packaging				
:	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	L	8 in 1 CARTON		
	1	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

l	Marketing Information				
Marketing Category Application Number or Monograph		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
l	OTC MONOGRAPH FINAL	part341	03/31/2016		

Part 2 of 2

DAYTIME COLD FLU RELIEF

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	
DEXTRO METHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTRO METHO RPHAN - UNII: 7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients		
Ingredient Name	Strength	
BUTYLATED HYDRO XYANISOLE (UNII: REK4960K2U)		
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)		
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)	
PO VIDO NE (UNII: FZ989 GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6 O 9 2 ICV 9 RU)	
SORBITOL (UNII: 506T60A25R)	
CARMINIC ACID (UNII: CID8 Z8 N9 5N)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics				
Color ORANGE		Score	no score	
Shape	CAPSULE	Size	21mm	
Flavor		Imprint Code	P19;95A;512;P119	
Contains				

	Item Code 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	03/31/2016		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/31/2016	

Labeler - Family Dollar (FAMILY WELLNESS) (024472631)

Revised: 12/2019 Family Dollar (FAMILY WELLNESS)