NON DROWSY DAY AND NIGHT MULTI-SYMPTOM COLD AND FLU FORMULAacetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride Family Dollar (FAMILY WELLNESS)

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# Non Drowsy DAY and NIGHT Multi-Symptom Cold and Flu Formula

# Active ingredients (in each softgel)

# Equate Health COLD & FLU FORMULA DAY NON-DROWSY

Acetaminophen 325 mg Dextromethorphan hydrobromide 10 mg Phenylephrine hydrochloride 5 mg

# Equate Health COLD & FLU FORMULA NIGHT

Acetaminophen 325 mg Dextromethorphan hydrobromide 10 mg Phenylephrine hydrochloride 5 mg

# **Purposes**

## **DAY COLD & FLU FORMULA**

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

#### **NIGHT COLD & FLU FORMULA**

Pain reliever/fever reducer

Cough suppressant

**Antihistamine** 

Nasal decongestant

#### Uses

#### **DAY COLD & FLU FORMULA**

temporarily relieves these symptoms due to a cold or flu: minor aches and pains headache cough sore throat nasal and sinus congestion temporarily reduces fever

#### **NIGHT COLD & FLU FORMULA**

Pain reliever/fever reducer

Cough suppressant

**Antihistamine** 

Nasal decongestant

#### undefined

# Liver warning

# **DAY COLD & FLU FORMULA**

These products contain acetaminophen. Severe liver damage may occur if you take

- more than 10 softgels in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

# 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.

**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.

#### **NIGHTTIME COLD & FLU FORMULA**

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- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

#### Do not use to sedate children.

#### Do not use

#### **DAY COLD & FLU FORMULA**

- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

#### **NIGHTTIME COLD & FLU FORMULA**

- 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.
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- in children under 12 years of age

# Ask a doctor before use if you have

#### **DAYTIME COLD & FLU FORMULA**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- cough with excessive phlegm (mucus)
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

#### **NIGHTTIME COLD & FLU FORMULA**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland

• persistent or chronic cough such as occurs with smoking, asthma, or emphysema

#### **DAYTIME COLD & FLU FORMULA**

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

#### **NIGHTTIME COLD & FLU FORMULA**

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

# When using this product

#### **DAYTIME COLD & FLU FORMULA**

# When using this product do not exceed recommended dosage

#### **NIGHTTIME COLD & FLU FORMULA**

- do not exceed recommended dosage
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

# Stop use and ask a doctor if

#### **DAYTIME COLD & FLU FORMULA**

- pain, cough, or 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.

nervousness, dizziness, or sleeplessness occurs

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These could be signs of a serious condition.

nervousness, dizziness, or sleeplessness occurs

If pregnant or breast-feeding, ask a health professional before use.

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#### **Directions**

#### DAY COLD & FLU FORMULA

- do not take more than the recommended dose
- adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 10 softgels in 24 hours or as directed by a doctor.
- children under 12 years: do not use

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- adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 10 softgels in 24 hours or as directed by a doctor.
- children under 12 years: do not use

#### Other information

• store at room temperature. Avoid excessive heat.

# Inactive ingredients

## **DAY COLD & FLU FORMULA**

FD&C Red# 40, FD&C Yellow# 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

## **NIGHTTIME COLD & FLU FORMULA**

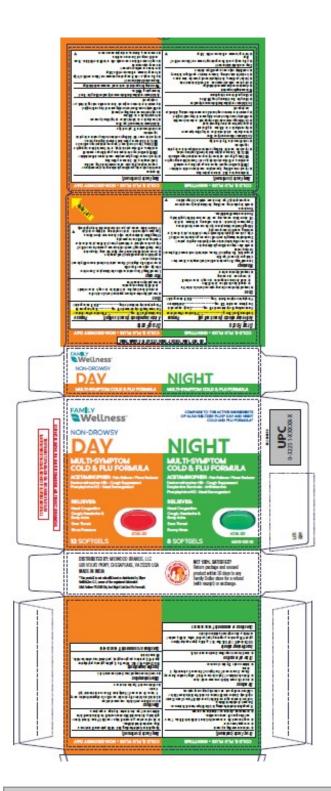
D&C Yellow No. 10, FD&C Blue No. 1, gelatin, glycerin, polyethylene, glycol-400, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan, sodium hydroxide, titanium dioxide

#### Questions or comments?

1-888-287-1915

Distributed by: MIDWOOD BRANDS, LLC 500 Volvo Pkwy Chesapeake, VA 23320 USA

# **Principal Display Panel**



**Packaging** 

# NON DROWSY DAY AND NIGHT MULTI-SYMPTOM COLD AND FLU FORMULA

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-615		

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-615- 20	1 in 1 CARTON; Type 1: Convenience Kit of Co- Package	04/06/2023	

Quantity	of	<b>Parts</b>
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Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	12
Part 2	1 BLISTER PACK	8

# Part 1 of 2

# **EQUATE HEALTH DAY COLD AND FLU PLUS**

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

# **Product Information**

Item Code (Source)	NDC:55319-613
Route of Administration	ORAL

Active Ingredient/Active Moiety						
Ingredient Name	<b>Basis of Strength</b>	Strength				
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg				
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg				
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE	5 mg				

Inactive Ingredients						
Ingredient Name	Strength					
FD&C RED NO. 40 (UNII: WZB9127XOA)						
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)						
GELATIN (UNII: 2G86QN327L)						
GLYCERIN (UNII: PDC6A3C0OX)						
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)						
POVIDONE (UNII: FZ989GH94E)						
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)						
SORBITOL (UNII: 506T60A25R)						
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)						

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Color	rod	Score	no score
Color	Teu	Score	no score

Shape	OVAL	Size	21mm
Flavor		Imprint Code	512;A09
Contains			

Pa	Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1		1 in 1 CARTON						
1		12 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 Drug	M012	04/06/2023				

# Part 2 of 2

# **EQUATE HEALTH NIGHTTIME COLD AND FLU PLUS**

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride capsule, liquid filled

Product Information		
Item Code (Source)	NDC:55319-614	
Route of Administration	ORAL	

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE	5 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 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6092ICV9RU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	green	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	116;A07
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		8 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 Drug	M012	04/06/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/06/2023	

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

Revised: 12/2023 Family Dollar (FAMILY WELLNESS)