# EQUATE HEALTH NON DROWSY DAY COLD AND FLU PLUS AND NIGHTTIME COLD AND FLU PLUS- acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride Wal-Mart Stores Inc

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### Equate Non Drowsy DAY Cold and Flu Formula and NIGHTTIME 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**

#### Liver warning

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.

#### 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.
- if you have ever had an allergic reaction to this product or any of its ingredients
- 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

#### NIGHTTIME COLD &FLU FORMULA

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- 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

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

#### **NIGHTTIME 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

#### 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

#### **Principal Display Panel**

Equate NON-DROWSY DAY Cold & Flu Formula and NIGHTTIME Cold & Flu Formula 20ct

Compare to the active ingredients in

Alka-Seltzer PLUS® Day and Night Cold and Flu Formula\*

**NON-DROWSY DAY** 

Cold & Flu Formula

ACETAMINOPHEN- Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr - Cough suppressant

PHENYLEPHRINE HCI - Nasal decongestant

Relieves:

Nasal congestion; Cough;

Headache & body ache;

Sore throat; Sinus pressure

12 SOFTGELS

**NIGHTTIME** 

Cold & Flu Formula

ACETAMINOPHEN- Pain reliever; Fever reducer

DEXTROMETHORPHAN HBr - Cough suppressant

DOXYLAMINE SUCCINATE - Antihistamine

PHENYLEPHRINE HCI - Nasal decongestant

Relieves:

Nasal congestion; Cough;

Headache & body ache;

Sore throat; Runny nose

8 SOFTGELS

THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND

TAMPER-EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT

\*This product is not manufactured or distributed by Bayer

Healthcare LLC, owner of the registered trademark

Alka-Seltzer PLUS  ${\mathbb R}$  Day and Night Cold and Flu Formula



## EQUATE HEALTH NON DROWSY DAY COLD AND FLU PLUS AND NIGHTTIME COLD AND FLU PLUS

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:79903-133

#### **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:79903-133- 20	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	08/11/2022	

Quantity of Parts				
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:79903-149 Route of Administration ORAL

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

Inactive Ingredients	
Ingredient Name	Strength
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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	red	Score	no score

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

Pa	Packaging				
#	ltem 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	08/11/2022		

#### Part 2 of 2

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

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

<b>Product Information</b>	
Item Code (Source)	NDC:79903-150
Route of Administration	ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<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	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 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			

Pa	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	08/11/2022		

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	08/11/2022		

### Labeler - Wal-Mart Stores Inc (051957769)

Revised: 12/2024 Wal-Mart Stores Inc