

**DAYTIME NON DROWSY COLD AND FLU AND NIGHTTIME COLD AND FLU-
acetaminophen, dextromethorphan hydrobromide, doxylamine succinate,
phenylephrine hydrochloride
Spirit Pharmaceuticals LLC**

Daytime Non Drowsy Cold and Flu and Nighttime Cold and Flu

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 10 mg
Doxylamine succinate 6.25 mg

Purposes

COLD & FLU NON DROWSY DAY RELIEF Pain reliever/fever reducer Cough suppressant Nasal decongestant
COLD & FLU NIGHT RELIEF Pain reliever/fever reducer Cough suppressant Antihistamine

Uses

- temporarily relieves common cold/flu symptoms:
- fever
- headache
- sore throat
- minor aches and pain
- cough due to minor throat and bronchial irritation
- nasal congestion (Daytime only)
- runny nose and sneezing (Nighttime only)

Warnings

Liver warning This product contains acetaminophen. Severe liver damage may occur if you take: ● more than 4 doses 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

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

- 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
- to make a child sleepy (Nighttime only)

Ask a doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- liver disease
- trouble urinating due to enlarged prostate gland
- diabetes (Daytime only)
- heart disease (Daytime only)
- thyroid disease (Daytime only)
- high blood pressure (Daytime only)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema (Daytime only)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema (Nighttime only)
- glaucoma (Nighttime only)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (Nighttime only)

When using this product

- **do not take more than directed**
- **marked drowsiness may occur (Nighttime only)**
- **avoid alcoholic drinks (Nighttime only)**
- **excitability may occur, especially in children (Nighttime only)**
- **be careful when driving a motor vehicle or operating machinery (Nighttime only)**
- **alcohol, sedatives, and tranquilizers may increase drowsiness (Nighttime only)**

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless (Daytime only)

- pain, nasal congestion, or cough gets worse or lasts more than 7 days (Daytime only)
 - pain or cough gets worse or lasts more than 7 days (Nighttime only)
 - 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.

Overdose warning Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults & for children even if you do not notice any signs or symptoms.

Directions (Daytime only)

- take only as directed - see Overdose warning
 - do not exceed 4 doses per 24 hours
 - adults and children 12 years and over: take 2 softgels with water every 4 hours
 - children 4 to under 12 years: ask a doctor
 - children under 4 years: do not use
 - when using other DAYTIME and NIGHTTIME products, carefully read each label to ensure correct dosing
- ### **Directions (Nighttime only)**
- take only as directed - see Overdose warning
 - do not exceed 4 doses per 24 hours
 - adults and children 12 years and over: take 2 softgels with water every 6 hours
 - children 4 to under 12 years: ask a doctor
 - children under 4 years: do not use
 - when using other DAYTIME and NIGHTTIME products, carefully read each label to ensure correct dosing

Other information

- store at room temperature.

Inactive ingredients

DAYTIME

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

NIGHTTIME

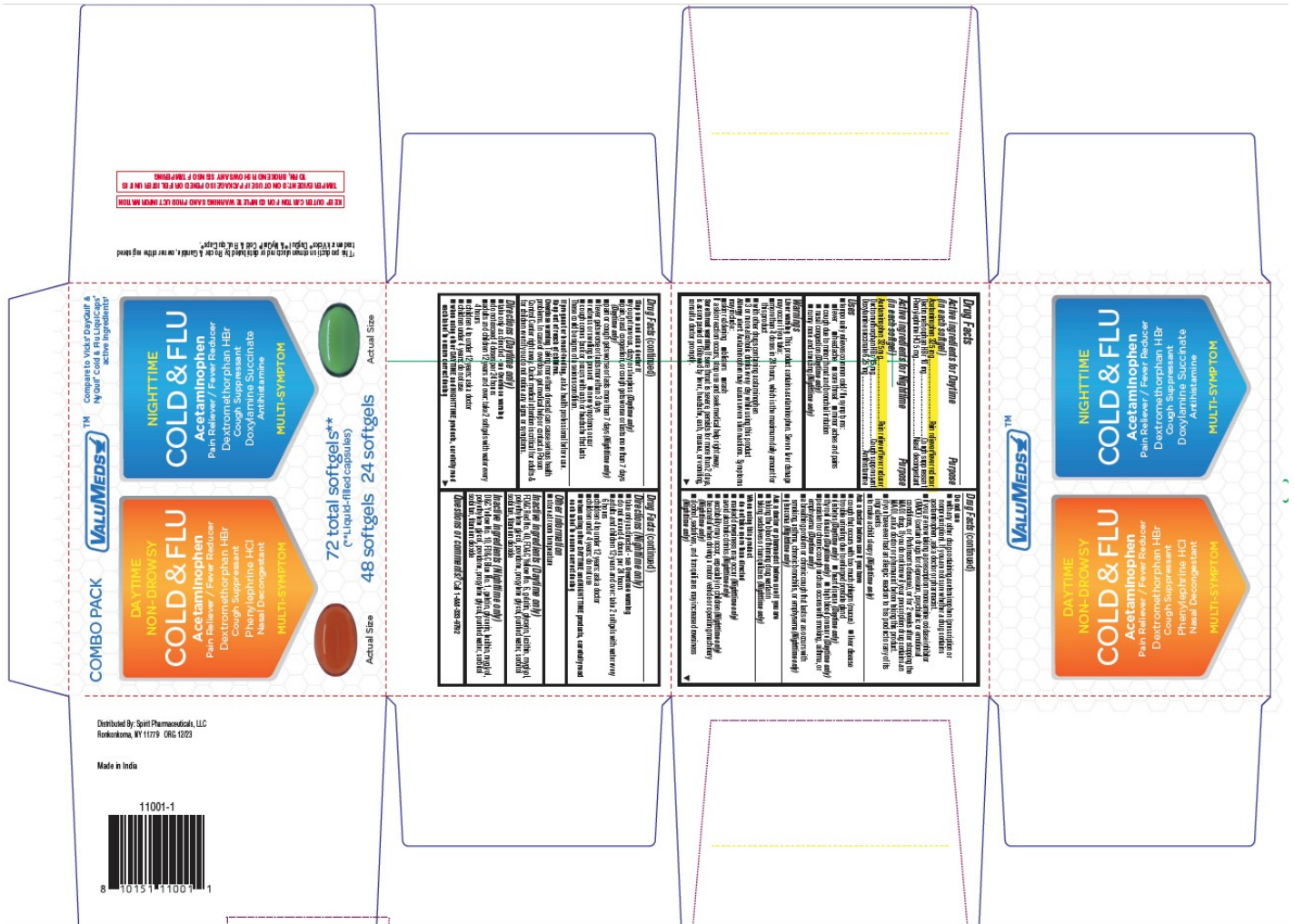
D&C Yellow# 10, FD&C Blue# 1, gelatin, glycerin, myglyol, lecithin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan, polysorb, sorbitol sorbitan,

titanium dioxide

Questions or comments?

1-888-333-9792

Principal Display Panel



DAYTIME NON DROWSY COLD AND FLU AND NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-5030
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:68210-5030-7	1 in 1 CARTON; Type 0: Not a Combination Product	12/20/2023
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Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	12
Part 2	1 BLISTER PACK	12

Part 1 of 2

DAYTIME NON DROWSY COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Product Information

Item Code (Source)	NDC:68210-5031
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	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)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	512;A09;AP01
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 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	12/20/2023	

Part 2 of 2

NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule, liquid filled

Product Information

Item Code (Source)	NDC:68210-5032
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
DOXYLAMINE SUCCINATE (UNII: V9B19B5Y12) (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)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	21mm
Flavor		Imprint Code	215;902;AP02
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 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	12/20/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/20/2023	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2023

Spirit Pharmaceuticals LLC