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

Cold and Flu Non Drowsy Daytime and Nighttime

Active ingredients (in each softgel)

COLD & FLU NON-DROWSY DAY RELIEF

Acetaminophen 325 mg
Dextromethorphan hydrobromide 10 mg
Phenylephrine hydrochloride 5 mg

COLD & FLU NIGHT RELIEF

Acetaminophen 325 mg
Dextromethorphan hydrobromide 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
- minor aches and pain
- cough due to minor throat and bronchial iffitation
- sore throat
- 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

● when using other DAYTIME and NIGHTTIME products, carefully read each label to ensure correct dosing

Directions (Daytime only)
● take only as directed - see Overdose warning
● do not exceed 4 doses per 24 hours

adults & children 12 years & over	take 2 softgels with water every 4 hours
children 4 to under 12 years	ask a doctor
children under 4 years of age	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 & children 12 years & over	take 2 softgels with water every 6 hours
children 4 to under 12 years	ask a doctor
children under 4 years of age	do not use

Other information

- store at room temperature.

Inactive ingredients

DAY RELIEF

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

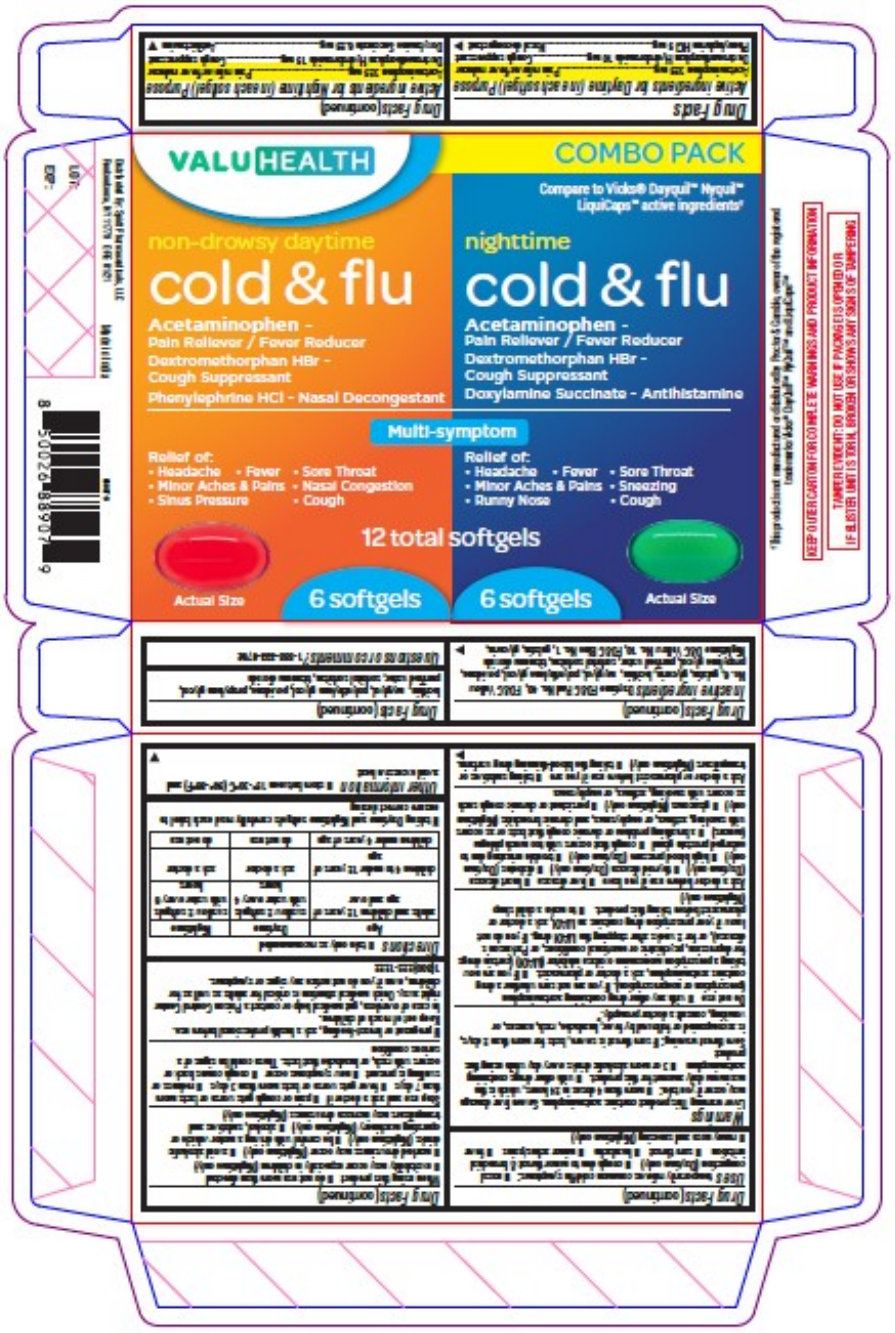
NIGHT RELIEF

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



COLD AND FLU NON DROWSY DAYTIME AND NIGHTTIME

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4214

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4214-1	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	10/19/2022	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	6
Part 2	6 BLISTER PACK	6

Part 1 of 2

COLD AND FLU NON DROWSY DAY RELIEF

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled

Product Information	
Item Code (Source)	NDC:68210-4212
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)	
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		1 in 1 CARTON		
1		6 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	10/19/2022	

Part 2 of 2

COLD AND FLU NIGHT RELIEF

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

Product Information

Item Code (Source)	NDC:68210-4213
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
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)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	**Score**	no score
Shape	OVAL	**Size**	21mm
Flavor		**Imprint Code**	116;A07;AP02
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 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 Drug	M012	10/19/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/19/2022	

Labeler - Spirit Pharmaceuticals LLC (179621011)

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