

**DAYTIME NIGHTTIME COLD AND FLU RELIEF MULTI-SYMPTOM-
acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine
hcl**

Spirit Pharmaceuticals LLC

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.

Non-Drowsy Daytime and Nighttime Combo Pack

Active ingredients in Daytime (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Active ingredients in 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
 - 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 pain
 - fever
 - runny nose and sneezing

Warnings

DAYTIME and NIGHTTIME

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

- more than 4 doses of acetaminophen in 24 hours
- 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

DAYTIME and 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

- diabetes
- 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 that lasts such as occur 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 exceed recommended dosage.

NIGHTTIME

- excitability may occur, especially in children
- avoid alcoholic drinks
- marked drowsiness may occur
- 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
- 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.

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 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.

DAYTIME and NIGHTTIME

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

Nighttime:

- **do not take more than directed (see Overdose warning)**
- do not take more than 4 doses in 24 hours
- adults and children 12 years and over: take 2 softgels with water every 6 hours
- children 4 to under 12 years of age: ask a doctor
- children under 4 years of age : do not use

Other information

DAYTIME and NIGHTTIME

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

Inactive ingredients

Daytime FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

Nighttime D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide

Questions or comments?

1-888-333-9792

PRINCIPAL DISPLAY PANEL

<p>Drug Facts (continued)</p> <p>Active ingredients for Daytime (in each softgel): Purpose Phenylephrine HCl 5 mg. Local decongestant Pseudoephedrine Hydrochloride 15 mg. Decongestant Acetaminophen 25 mg. Pain reliever/fever reducer Dextromethorphan HBr 1 mg. Cough suppressant Doxylamine Succinate 2 mg. Sedating antihistamine Compare to Vicks® DayQuil™ and NyQuil™ "Lightly" active ingredients!</p>		<p>Drug Facts (continued)</p> <p>Active ingredients for Nighttime (in each softgel): Purpose Doxylamine Succinate 2 mg. Sedating antihistamine Acetaminophen 25 mg. Pain reliever/fever reducer Dextromethorphan HBr 1 mg. Cough suppressant Doxylamine Succinate 2 mg. Sedating antihistamine</p>	
<p align="center"> SPRIT 360 COMBO PACK non-drowsy daytime cold & flu nighttime cold & flu Multi-symptom 12 total softgels 6 softgels 6 softgels Actual Size Actual Size </p> <p>Acetaminophen - Pain Reliever /Fever Reducer Dextromethorphan HBr - Cough Suppressant Phenylephrine HCl - Nasal Decongestant</p> <p>Relief of: • Headache • Fever • Sore Throat • Minor Aches & Pains • Nasal Congestion • Sinus Pressure • Cough</p>			
<p>Warnings (continued)</p> <p>Use temporarily unless otherwise indicated: • Use if you have had a heart attack, heart disease, or have a history of heart disease. • Do not use if you have had a stroke or are at risk for a stroke. • Do not use if you have a history of high blood pressure or are at risk for high blood pressure. • Do not use if you have a history of asthma or are at risk for asthma. • Do not use if you have a history of glaucoma or are at risk for glaucoma. • Do not use if you have a history of kidney disease or are at risk for kidney disease. • Do not use if you have a history of liver disease or are at risk for liver disease. • Do not use if you have a history of stomach disease or are at risk for stomach disease. • Do not use if you have a history of thyroid disease or are at risk for thyroid disease. • Do not use if you are pregnant, trying to get pregnant, or breastfeeding. • Do not use if you are taking other drugs containing acetaminophen, dextromethorphan, doxylamine, or pseudoephedrine. • Do not use if you are taking other drugs containing antihistamines. • Do not use if you are taking other drugs containing decongestants. • Do not use if you are taking other drugs containing cough suppressants. • Do not use if you are taking other drugs containing sedatives. • Do not use if you are taking other drugs containing tranquilizers. • Do not use if you are taking other drugs containing antidepressants. • Do not use if you are taking other drugs containing anti-anxiety drugs. • Do not use if you are taking other drugs containing anti-seizure drugs. • Do not use if you are taking other drugs containing anti-cancer drugs. • Do not use if you are taking other drugs containing anti-inflammatory drugs. • Do not use if you are taking other drugs containing anti-infective drugs. • Do not use if you are taking other drugs containing anti-blood clotting drugs. • Do not use if you are taking other drugs containing anti-diabetic drugs. • Do not use if you are taking other drugs containing anti-epileptic drugs. • Do not use if you are taking other drugs containing anti-hypertensive drugs. • Do not use if you are taking other drugs containing anti-neoplastic drugs. • Do not use if you are taking other drugs containing anti-obesity drugs. • Do not use if you are taking other drugs containing anti-ulcer drugs. • Do not use if you are taking other drugs containing anti-viral drugs. • Do not use if you are taking other drugs containing anti-worming drugs. • Do not use if you are taking other drugs containing anti-zoster drugs. • Do not use if you are taking other drugs containing anti-cancer drugs. • Do not use if you are taking other drugs containing anti-infective drugs. • Do not use if you are taking other drugs containing anti-blood clotting drugs. • Do not use if you are taking other drugs containing anti-diabetic drugs. • Do not use if you are taking other drugs containing anti-epileptic drugs. • Do not use if you are taking other drugs containing anti-hypertensive drugs. • Do not use if you are taking other drugs containing anti-neoplastic drugs. • Do not use if you are taking other drugs containing anti-obesity drugs. • Do not use if you are taking other drugs containing anti-ulcer drugs. • Do not use if you are taking other drugs containing anti-viral drugs. • Do not use if you are taking other drugs containing anti-worming drugs. • Do not use if you are taking other drugs containing anti-zoster drugs.</p>			
<p>Drug Facts (continued)</p> <p>Other information: • Contains 12 total softgels (6 daytime and 6 nighttime). • Each softgel contains 25 mg acetaminophen, 1 mg dextromethorphan HBr, 5 mg phenylephrine HCl, and 2 mg doxylamine succinate. • Contains 6 softgels (6 nighttime). • Each softgel contains 25 mg acetaminophen, 1 mg dextromethorphan HBr, 2 mg doxylamine succinate, and 1 mg pseudoephedrine HCl. • Contains 6 softgels (6 daytime). • Each softgel contains 25 mg acetaminophen, 1 mg dextromethorphan HBr, 5 mg phenylephrine HCl, and 1 mg pseudoephedrine HCl. • Contains 6 softgels (6 nighttime). • Each softgel contains 25 mg acetaminophen, 1 mg dextromethorphan HBr, 2 mg doxylamine succinate, and 1 mg pseudoephedrine HCl. • Contains 6 softgels (6 daytime). • Each softgel contains 25 mg acetaminophen, 1 mg dextromethorphan HBr, 5 mg phenylephrine HCl, and 1 mg pseudoephedrine HCl. • Contains 6 softgels (6 nighttime). • Each softgel contains 25 mg acetaminophen, 1 mg dextromethorphan HBr, 2 mg doxylamine succinate, and 1 mg pseudoephedrine HCl. • Contains 6 softgels (6 daytime). • Each softgel contains 25 mg acetaminophen, 1 mg dextromethorphan HBr, 5 mg phenylephrine HCl, and 1 mg pseudoephedrine HCl. • Contains 6 softgels (6 nighttime). • Each softgel contains 25 mg acetaminophen, 1 mg dextromethorphan HBr, 2 mg doxylamine succinate, and 1 mg pseudoephedrine HCl.</p>			
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DAYTIME NIGHTTIME COLD AND FLU RELIEF MULTI-SYMPTOM
 acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-4193
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-4193-1	1 in 1 CARTON; Type 0: Not a Combination Product	12/30/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	6
Part 2	1 BLISTER PACK	6

Part 1 of 2**NIGHTTIME COLD AND FLU**

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate capsule

Product Information

Route of Administration	ORAL
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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)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	green	Score	no score
Shape	CAPSULE (OBLONG)	Size	20mm
Flavor		Imprint Code	215;902
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 final	part341	12/30/2021	

Part 2 of 2

DAYTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, phenylephrine hcl capsule

Product Information

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 HYDROCHLORIDE	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 K30 (UNII: U725QWY32X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red (ORANGE TO RED)	Score	no score
Shape	CAPSULE (OBLONG)	Size	20mm
Flavor		Imprint Code	512;A09
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 final	part341	03/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/30/2021	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2021

Spirit Pharmaceuticals LLC