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: \bullet skin reddening \bullet blisters \bullet 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

- ullet cough that occurs with too much phlegm (mucus) ullet 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

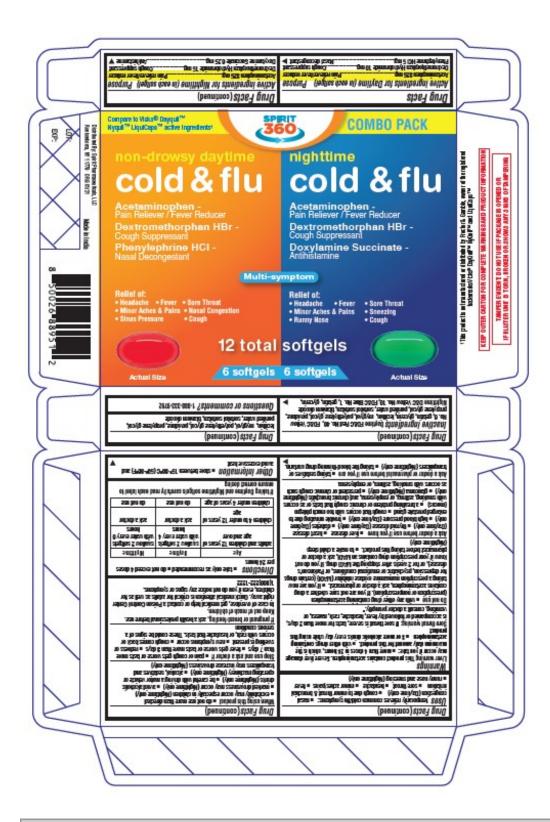
NIGHT RELIEF

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 Informat	ion		
Product Type	HUMAN OTC DRUG	ltem Code (Source)	NDC:68210-4217

Pacl	kaging								
# It	em Code	Pa	ckage Description	ı	Mar	keting Start Date		ting End ate	
	C:68210- 17-1	1 in 1 CARTON Package	ON; Type 1: Convenience Kit of Co-		10/19/2022				
-	ntity of P								
Part		Package C	uantity		To	tal Product Qu	uantity		
Part 1 Part 2				6					
Part 2		PACK		0					
Par	t 1 of 2								
			DROWSY DA orphan hydrobrom			ne hydrochloric	le capsul	e, liquid	
Pro	duct Infor	mation							
ltem	Code (Sou	rce)	NDC:68210-4215						
Rout	e of Admin:	istration	ORAL						
Activ	ve Ingred	ient/Active	Moiety						
		Ingred	lient Name			Basis of St	rength	Strengt	
ACET	AMINOPHEN	(UNII: 36209ITL	9D) (ACETAMINOPHEN	- UNII:36209	ITL9D)	ACETAMINOPHEN		325 mg	
		Phan Hydrobi Ian - Unii:7355x	ROMIDE (UNII: 9D2RTIS 3ROTS)	ЭКҮН)		DEXTROMETHORI HYDROBROMIDE	PHAN	10 mg	
	WS297W6MV)	HYDROCHLORI	DE (UNII: 04JA59TNSJ)	(PHENYLEPH	RINE -	PHENYLEPHRINE		5 mg	
Inac	tive Ingre	edients							
	inte nigre		Ingredient Nam	e			St	rength	
FD&C	RED NO. 40) (UNII: WZ B912					J		
		D. 6 (UNII: H77V							
GELA	TIN (UNII: 2G8	86QN327L)							
GLYC	ERIN (UNII: PI	DC6A3C0OX)							
LECIT	THIN, SOYBE	AN (UNII: 1DI560	QDM62)						
			(UNII: C9H2L21V7U)						
			NII: B697894SGQ)						
	DONE (UNII: F								
		OL (UNII: 6DC90	Q167V3)						
	ITOL (UNII: 5								
TITAN	NUM DIOXID	E (UNII: 15FIX9V	2JP)						

Product C	haracte	eristics						
Color		red		Score		no score		
Shape		OVAL		Size		21mm		
Flavor				Imprint Code		512;A09;AP	01	
Contains								
Packaging	1							
ltom	, 		_		Mark	eting Start	Marke	ting End
# Code		Pack	age De	escription		Date		ate
1	1 in 1 CA	ARTON						
1	6 in 1 BL Product	LISTER PAC	СК; Туре (0: Not a Combination				
Marketi	ng Inf	ormat	ion					
Marketi Catego		Applicat		mber or Monograph itation	Ма	rketing Start Date		eting End Date
OTC Monograp	h Drug M	1012			10/19	/2022		
	()							
Part 2 o	f 2							
Part 2 o COLD AN		J NIGI	HT RE	LIEF				
COLD AN				ELIEF hydrobromide, doxyl	amine s	uccinate, pher	nylephrin	e
COLD AN	ND FLU hen, dex	trometh	orphan		amine s	uccinate, pher	nylephrin	le
COLD AN acetaminop	ND FLU hen, dex	trometh	orphan		amine s	succinate, pher	nylephrin	e
COLD AN acetaminop	ND FLU hen, dex	trometh	orphan		amine s	succinate, pher	nylephrin	e
COLD AN acetaminop hydrochlorid	ND FLU hen, dex de capsu	ktrometh lle, liquid	orphan		amine s	uccinate, pher	nylephrin	e
COLD AN acetaminop hydrochlorid	ND FLU hen, dex de capsu	ktrometh lle, liquid	orphan filled	hydrobromide, doxyl	amine s	succinate, pher	nylephrin	le
COLD AN acetaminop hydrochlorid Product In Item Code (ND FLU hen, dex de capsu nformat Source)	ktrometh lle, liquid	orphan filled NDC:68		amine s	uccinate, pher	nylephrin	le
COLD AN acetaminop hydrochlorid	ND FLU hen, dex de capsu nformat Source)	ktrometh lle, liquid	orphan filled	hydrobromide, doxyl	amine s	uccinate, pher	nylephrin	le
COLD AN acetaminop hydrochlorid Product In Item Code (ND FLU hen, dex de capsu nformat Source)	ktrometh lle, liquid	orphan filled NDC:68	hydrobromide, doxyl	amine s	uccinate, pher	nylephrin	le
COLD AN acetaminop hydrochlorid Product In Item Code (Route of Ad	ND FLU hen, dex de capsu nformat Source)	tion	orphan filled NDC:68 ORAL	hydrobromide, doxyl 210-4216	amine s	succinate, pher	nylephrin	le
COLD AN acetaminop hydrochlorid Product In Item Code (ND FLU hen, dex de capsu nformat Source)	tion /Active	orphan filled NDC:68 ORAL Moiety	hydrobromide, doxyl 210-4216	amine s			
COLD AN acetaminop hydrochlorid Product In Item Code (Route of Ad	ND FLU hen, dex de capsu nformat Source) ministra redient,	tion /Active Ingred	orphan filled NDC:68 ORAL Moiety dient N	hydrobromide, doxyl 210-4216 Y ame		Basis of Str		Strength
COLD AN acetaminop hydrochlorid Product In Item Code (Route of Ad Active Ing	ND FLU hen, dex de capsu nformat Source) ministra redient,	tion /Active Ingred : 36209ITL	orphan filled NDC:68 ORAL Moiety dient N _9D) (ACE	hydrobromide, doxyl 210-4216 Y ame :TAMINOPHEN - UNII:3620		Basis of Sti ACETAMINOPHEN	rength	
COLD AN acetaminop hydrochlorid Product In Item Code (Route of Ad Active Ing Acetaminop Dextrometh (Dextrometh	ND FLU hen, dex de capsu format Source) ministra redient, redient,	tion /Active Ingred : 36209ITL HYDROBI	NDC:68 ORAL Moiety dient N -9D) (ACE ROMIDE (3ROTS)	hydrobromide, doxyl 210-4216 Y ame TAMINOPHEN - UNII:3620 (UNII: 9D2RTI9KYH)		Basis of Str	rength	Strength
COLD AN acetaminop hydrochlorid Product In Item Code (Route of Ad Active Ing ACETAMINOP DEXTROMETH	ND FLU hen, dex de capsu format Source) ministra redient, HEN (UNII: HORPHAN - U SUCCINA	tion /Active Ingred : 36209ITL HYDROBI	NDC:68 ORAL Moiety dient N -9D) (ACE ROMIDE (3ROTS)	hydrobromide, doxyl 210-4216 Y ame :TAMINOPHEN - UNII:3620		Basis of Sti ACETAMINOPHEN DEXTROMETHORP	r ength PHAN	Strength 325 mg
COLD AN acetaminop hydrochlorid Product In Item Code (Route of Ad Active Ing Acetaminop Dextrometho (Dextrometho DoxyLamine	ND FLU hen, dex de capsu format Source) ministra redient, HEN (UNII: HORPHAN - U SUCCINA	tion /Active Ingred : 36209ITL HYDROBI	NDC:68 ORAL Moiety dient N -9D) (ACE ROMIDE (3ROTS)	hydrobromide, doxyl 210-4216 Y ame TAMINOPHEN - UNII:3620 (UNII: 9D2RTI9KYH)		Basis of Stu ACETAMINOPHEN DEXTROMETHORP HYDROBROMIDE	r ength PHAN	Strength 325 mg 10 mg
COLD AN acetaminop hydrochlorid Product In Item Code (Route of Ad Active Ing Acetaminop Dextrometho (Dextrometho DoxyLamine	ND FLU hen, dex de capsu format Source) ministra redient, HEN (UNII: HORPHAN - U SUCCINA PL)	tion /Active Ingred : 36209ITL HYDROBI UNII: 7355X	NDC:68 ORAL Moiety dient N -9D) (ACE ROMIDE (3ROTS)	hydrobromide, doxyl 210-4216 Y ame TAMINOPHEN - UNII:3620 (UNII: 9D2RTI9KYH)		Basis of Stu ACETAMINOPHEN DEXTROMETHORP HYDROBROMIDE	r ength PHAN	Strength 325 mg 10 mg
COLD AN acetaminop hydrochlorid Product In Item Code (Route of Ad Active Ing Acetaminop Dextromethor (DEXTROMETHO DOXYLAMINE UNII:95QB77JK	ND FLU hen, dex de capsu format Source) ministra redient, HEN (UNII: HORPHAN - U SUCCINA PL)	tion /Active Ingred : 36209ITL HYDROBI UNII: 7355X	orphan filled NDC:68 ORAL ORAL Moiety dient N _9D) (ACE ROMIDE (3ROTS) V9BI9B5Y	hydrobromide, doxyl 210-4216 Y ame TAMINOPHEN - UNII:3620 (UNII: 9D2RTI9KYH)		Basis of Stu ACETAMINOPHEN DEXTROMETHORP HYDROBROMIDE	rength PHAN CINATE	Strength 325 mg 10 mg
COLD AN acetaminop hydrochlorid Product In Item Code (Route of Ad Active Ing AcetaMinop Dextrometry (Dextrometry UNII:95QB77JK	ND FLU hen, dex de capsu format Source) ministra redient, HEN (UNII: HORPHAN - U SUCCINA PL) ngredier	tion /Active ingred : 36209ITL HYDROBI UNII: 7355X ATE (UNII: N nts	NDC:68 NDC:68 ORAL Moiety dient N 9D) (ACE ROMIDE (3ROTS) V9BI9B5Y V9BI9B5Y	hydrobromide, doxyl 210-4216 y lame TAMINOPHEN - UNII:3620 (UNII: 9D2RTI9KYH) (12) (DOXYLAMINE -		Basis of Stu ACETAMINOPHEN DEXTROMETHORP HYDROBROMIDE	rength PHAN CINATE	Strength 325 mg 10 mg 6.25 mg
COLD AN acetaminop hydrochlorid Product In Item Code (Route of Ad Active Ing AcetAMINOP DEXTROMETH DOXYLAMINE UNII:95QB77JK	ND FLU hen, dex de capsu format Source) ministra redient, HEN (UNII: HORPHAN - U SUCCINA PL) ngredien	tion /Active ingred : 36209ITL HYDROBI UNII: 7355X ATE (UNII: N Ints UNII: 355W I: H3R47K3	NDC:68 NDC:68 ORAL Moiety dient N 9D) (ACE ROMIDE (3ROTS) V9BI9B5Y V9BI9B5Y	hydrobromide, doxyl 210-4216 y lame TAMINOPHEN - UNII:3620 (UNII: 9D2RTI9KYH) (12) (DOXYLAMINE -		Basis of Stu ACETAMINOPHEN DEXTROMETHORP HYDROBROMIDE	rength PHAN CINATE	Strength 325 mg 10 mg 6.25 mg

LECTI HIN. SUTBE	AN (UNII: 1DI56QDM6	52)		
•	RIGLYCERIDES (UNII			
	LYCOL 400 (UNII: B			
POVIDONE (UNII: F	Z989GH94E)			
PROPYLENE GLYC	OL (UNII: 6DC9Q167)	V3)		
SORBITOL (UNII: 5	06T60A25R)			
SORBITAN (UNII: 6	092ICV9RU)			
TITANIUM DIOXID	E (UNII: 15FIX9V2JP)			
Product Chara	octorictics			
Color		Score	no 5 5 6	ro
	green	Size	no sco 21mm	
Shape Flavor	OVAL			07;AP02
		Imprint Code	110;AU	17;APU2
Contains				
Packaging				
ltom	Package	Description	Marketing Start Date	Marketing End Date
# Item Code	Package	Description		
# Item Code 1 1 ir 1 1 ir	1 CARTON 1 BLISTER PACK; Ty	Description		
# Item Code 1 1 ir 1 1 ir	1 CARTON	-		
Item Code 1 1 1	1 CARTON 1 BLISTER PACK; Ty	-		
Item Code 1 1 1 1 Pro	1 CARTON 1 BLISTER PACK; Ty duct	pe 0: Not a Combination		
Item Code 1 1 1 ir 1 1 ir 1 Pro	1 CARTON 1 BLISTER PACK; Ty duct	pe 0: Not a Combination	Date	Date
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# Item Code 1 1 ir 1 1 Pro Marketing Category	1 CARTON 1 BLISTER PACK; Ty duct Information Application	pe 0: Not a Combination Number or Monograph	Date Marketing Sta	Date rt Marketing End
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Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 12/2023

Spirit Pharmaceuticals LLC