COLD AND FLU NON DROWSY DAY RELIEF AND NIGHT RELIEFacetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride Gobrands, Inc

Cold and Flu Non Drowsy Day Relief and Night Relef

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, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide*, MYGLYOL 812*, lecithin*

*May Contain one or more of these ingredients

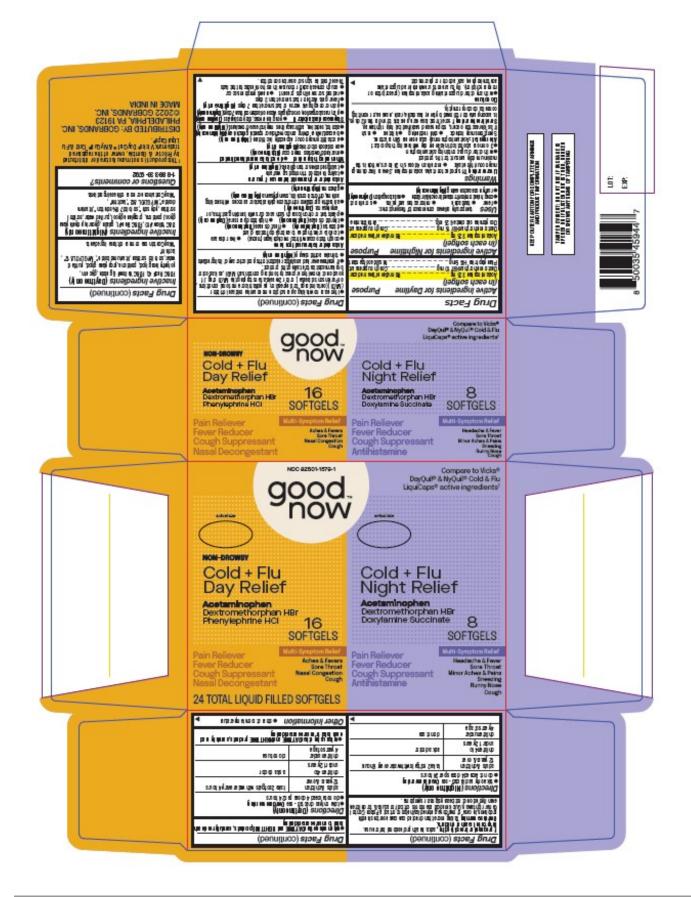
NIGHT RELIEF

D&C Yellow# 10, FD&C Blue# 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan, polysorb*, sorbitol 70% solution*, titanium dioxide*, MYGLYOL 812*, lecithin*, *May Contain one or more of these ingredients

Questions or comments?

1-888-333-9792

Principal Display Panel



COLD AND FLU NON DROWSY DAY RELIEF AND NIGHT RELIEF acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hydrochloride kit

Product Type	ΗΠΜΑΝΙ (OTC DRUG	ltem Code	(Source	a)	NDC:82501-	1579
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	Ingredient Name						
D&C YELLOW NO. 10 (UNII: 3							
D&C BLUE NO. 1 (UNII: H3R47K3TBD)							
GELATIN (UNII: 2G86QN327L)	GELATIN (UNII: 2G86QN327L)						
GLYCERIN (UNII: PDC6A3C0OX)							
POLYETHYLENE GLYCOL 400	(UNII: B697894S	GQ)					
POVIDONE (UNII: FZ989GH94E)						
PROPYLENE GLYCOL (UNII: 60	C9Q167V3)						
SORBITOL (UNII: 506T60A25R)							
SORBITAN (UNII: 6092ICV9RU)							
TITANIUM DIOXIDE (UNII: 15FI	X9V2JP)						
LECITHIN, SOYBEAN (UNII: 1D	156QDM62)						
Product Characteristic	CS						
Color	green	Score		no score			
Shape	OVAL	Size		21mm			
Flavor		Imprint Code		116;A07			

Packaging

Contains

#	ltem 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	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M012	09/08/2022	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M012	09/08/2022	

Labeler - Gobrands, Inc (057499049)

Registrant - Spirit Pharmaceuticals LLC (179621011)

Establishment						
Name	Address	ID/FEI	Business Operations			
MEDGEL PRIVATE LIMITED		677385498	manufacture(82501-1579)			

Establishment						
Name	Address	ID/FEI	Business Operations			
Elysium Pharmaceuticals Ltd		863182240	manufacture(82501-1579)			

Revised: 12/2023

Gobrands, Inc