COLD AND FLU NON DROWSY DAY RELIEF AND NIGHT RELIEF- acetaminophen, 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: ● 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, povidone, propylene glycol, purified water, sorbitol sorbitan, titanium dioxide*, MYGLYOL 812*, lecithin*
*May Contain one or more of these ingredients

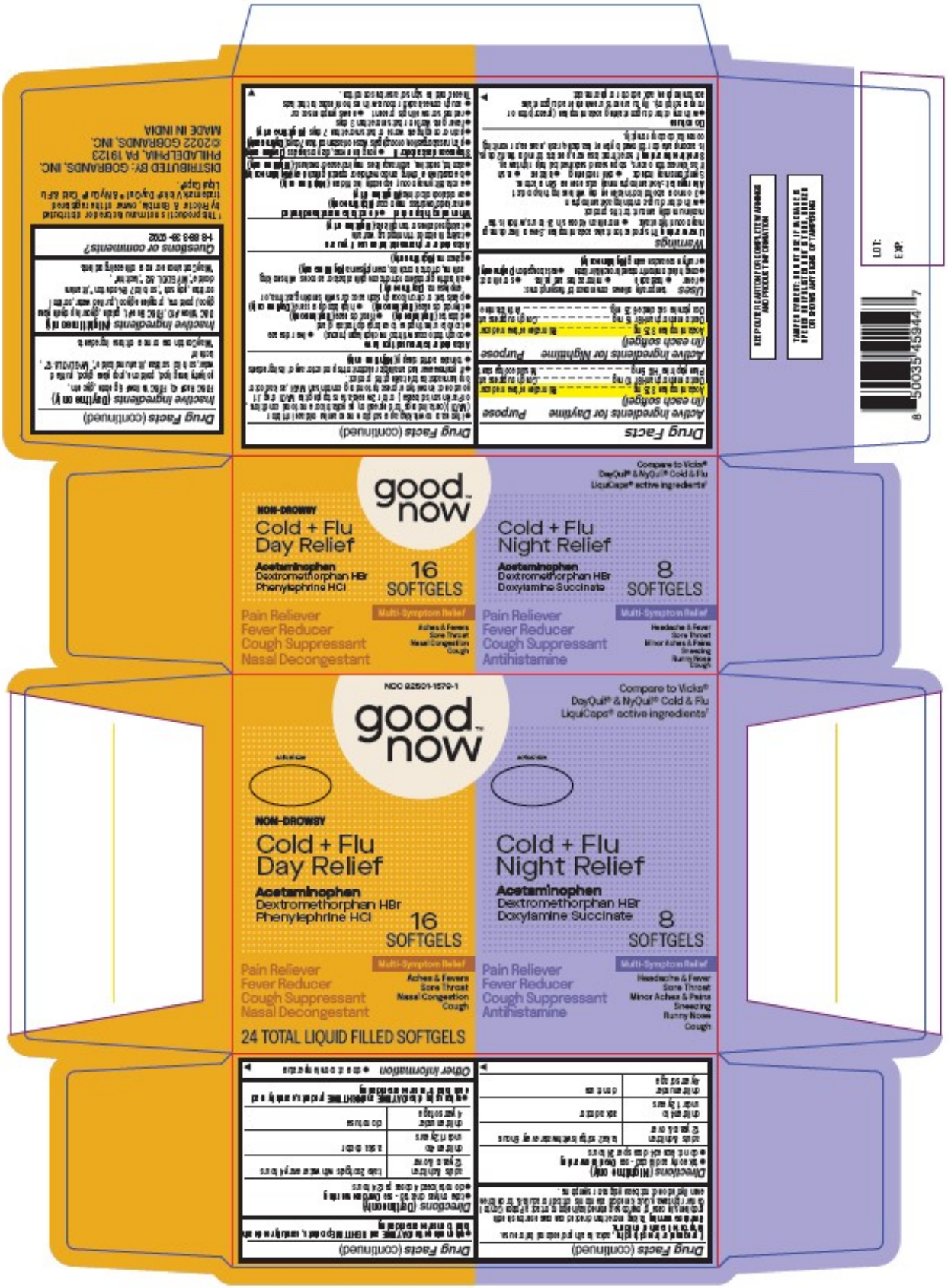
NIGHT RELIEF

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 Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82501-1579

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:82501-1579-1	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	09/08/2022	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	8
Part 2	1 BLISTER PACK	8

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:82501-1583
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)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		16 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	09/08/2022	

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:82501-1584
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)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

Product Characteristics

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

Packaging

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

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End 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