DAYTIME NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl
Strive Pharmaceuticals Inc.

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.

DAYTIME NIGHTTIME COLD and FLU

Active ingredients (in each Softgel) (Daytime)	Purpose
Acetaminophen 325mg	Pain Reliever/fever reducer
Dextromethorphan HBr 10mg	Cough suppressant
Phenylephrine HCl 5mg	Nasal Decongestant

Active ingredients (in each Softgel) (Nighttime)	Purpose
Acetaminophen 325mg	Pain Reliever/fever reducer
Dextromethorphan HBr 15mg	Cough suppressant
Docylamine Succinate 6.25mg	Antihistamine

Daytime

Pain reliever/fever reducer, Cough suppresant and Nasal decongestant

Nighttime

Pain reliever/fever reducer, Cough suppressant and Antihistamine

* temporarily relieves common cold/flu symptoms:
- nasal congestion (Daytime only)
- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever
- runny nose and sneezing (Nighttime only)

Liver warning:
This product contains acetaminophen. Severe liver damage may occur if you take:
*more than 4 doses in 24 hrs, 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.

*to make a child sleep (Nighttime only).

Ask a doctor before use if you have

* liver disease
* heart disease (Daytime only)
* high blood pressure (Daytime only)
* thyroid disease (Daytime only)
* trouble urinating due to an enlarged prostate gland
* glaucoma (Nighttime only)
* persistent or chronic cough such as occurs with smoking, asthma or emphysema and (Nighttime only) chronic bronchitis
* cough that occurs with too much phlegm (mucus)

Ask a doctor or a pharmacist before use if you are
* taking the blood thinning drug warfarin
* taking sedatives or tranquilizers (Nighttime only)

When using this product
Do not use more than directed. In addition when using Nighttime:
* excitability may occur, especially in children
* marked drowsiness may occur
* alcohol, sedatives, and tranquilizers may increase drowsiness
* be careful when driving a motor vehicle or operating machinery
* avoid alcoholic drinks

Stop use and ask a doctor if
* you get nervous, dizzy, or sleepless (Daytime only)
* pain, cough and nasal congestion (Daytime only) may get worse or lasts more than 7 days
* new symptoms occur
* fever gets worse or lasts more than 3 days
* redness or swelling is present
* 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 care 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.

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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.

Directions
* take only as directed - see OVERDOSE WARNING

* do not exceed 4 doses per 24 hrs
* take softgels with water

Read each label carefully before taking Daytime and Nighttime product

	Daytime	Nighttime
adulta & children age 12 years & over	2 softgels every 4 hours	2 softgels every 6 hours
children 4 to under 12 years	ask a doctor	ask a doctor
children under 4 years	do not use	do not use

Other information
* store at room temperature between 20 - 25°C (68 - 77°F)

*avoid excessive heat, cold and humidity

Inactive ingredients (Daytime)
FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide.

Inactive ingredients (Nighttime)
D&C yellow #10, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide.

DAYTIME NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70692-602

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70692-602-12	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	11/06/2018	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	8
Part 2	1 BLISTER PACK	4

Part 1 of 2

DAYTIME NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr , phenylephrine hcl capsule, liquid filled

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POVIDONE (UNII: FZ989GH94E)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics			
Color	red	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	604
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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 final	part341	11/06/2018	

Part 2 of 2

DAYTIME NIGHTTIME COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate capsule, liquid filled

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SORBITOL (UNII: 506T60A25R)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	green	**Score**	no score

Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	603
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		4 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	11/06/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	11/06/2018	

Labeler - Strive Pharmaceuticals Inc. (080028013)

Revised: 4/2022 Strive Pharmaceuticals Inc.