MULTI SYMPTOM SINUS RELIEF PAIN AND CONGESTION DAYTIME NIGHTTIME-
acetaminophen, diphenhydramine hcl, guaifenesin, 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.

MULTI-SYMPTOM SINUS RELIEF
PAIN & CONGESTION
MAXIMUM STRENGTH DAYTIME AND NIGHTTIME

Active ingredients (in each caplet) (Daytime)	Purpose
Acetaminophen 325mg	Pain Reliever
Guaifenesin 200mg	Expectorant
Phenylephrine HCl 5mg	Nasal Decongestant

Active ingredients (in each caplet) (Nighttime)	Purpose
Acetaminophen 325mg	Pain Reliever
Diphenhydramine 12.5mg	Anthistamine/Cough suppressant
Phenylephrine HCl 5mg	Nasal Decongestant

Daytime

Pain reliever, Expectorant and Nasal decongestant

Nighttime

Pain reliever, Antihistamine/cough suppressant and Nasal decongestant

* temporarily relieves:
- nasal congestion
- headache
- minor aches and pain
- sinus congestion and pressure
- runny nose and sneezing (Nighttime only)
- cough (Nighttime only)

* temporarily promotes nasal and/or sinus drainag

* helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (Daytime only)

Liver warning:
This product contains acetaminophen. Severe liver damage may occur if you take:
*more than 12 caplets in 24 hrs, which is the maximum daily amount
* 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.

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 have ever had an allergic reaction to this product or any of its ingredients
* with any other drug containing diphenhydramine, even one used on the skin (Nighttime only)
* 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

* liver disease
* heart disease
* diabetes
* high blood pressure
* thyroid disease
* trouble urinating due to an enlarged prostate gland
* glaucoma (Nighttime only)
* a breathing problem such as emphysema or chronic bronchitis (Nighttime only)
* persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
* 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 exceed recommended dose
* excitability may occur, especially in children (Nighttime only)
* marked drowsiness may occur (Nighttime only)
* alcohol, sedatives, and tranquilizers may increase drowsiness (Nighttime only)
* be careful when driving a motor vehicle or operating machinery (Nighttime only)
* avoid alcoholic beverages (Nighttime only)

Stop use and ask a doctor if
* nervousness, dizziness, or sleeplessness occur
* pain, nasal congestion, or cough gets 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 professional before use.

Keep out of reach of children
In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

If taking Nighttime and Daytime products,
carefully read each section to ensure correct dosing
Do not take **DAYTIME** and **NIGHTTIME** at the same time

Keep out of reach of children
In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions
* Do not use more than directed
* swallow whole with a glass of water; do not crush, chew or dissolve
* do not take more than 12 caplets in 24 hours

adults and children 12 years of age and over	take 2 caplets every 4 hours
children under 12 years of age	do not take

Other information
* each Nighttime caplet contains: Calcium 40mg or less
* store at room temperature 25°C (77°F) ; excursions permitted between 15°C - 30°C (59°F -86°F)

Inactive ingredients (Daytime)
microcrystalline cellulose, dibasic calcium phosphate, croscarmellose sodium, talc, colloidal silicon dioxide, stearic acid, magnesium stearate, polyvinyl alcohol, polyethylene glycol, titanium dioxide,FD&C yellow #6, FD&C red #40, gelatin, starch, polyvinyl povidone, maltodextrin, sodium starch glycolate

Inactive ingredients (Nightime)
microcrystalline cellulose, dibasic calcium phosphate, corn starch, croscarmellose sodium, talc, colloidal silicon dioxide, stearic acid, magnesium stearate, polyvinyl alcohol, polyethylene glyocol, mica, titanium dioxide, FD&C blue #1, methacrylic acid copolymer, FD&C blue #2, sodium bicarbonate, starch, gelatin, sodium starch glycolate

MULTI SYMPTOM SINUS RELIEF PAIN AND CONGESTION DAYTIME NIGHTTIME

acetaminophen, diphenhydramine hcl, guaifenesin, phenylephrine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70692-103

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70692-103-12	1 in 1 PACKAGE, COMBINATION; Type 0: Not a Combination Product	03/01/2018	

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

MULTI SYMPTOM SINUS RELIEF PAIN AND CONGESTION DAYTIME

acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 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**
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TALC (UNII: 7SEV7J4R1U)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
GELATIN (UNII: 2G86QN327L)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	orange (Reddish Orange)	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	S703
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	03/01/2018	

Part 2 of 2

MULTI SYMPTOM SINUS RELIEF PAIN AND CONGESTION NIGHTTIME

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride tablet, film coated

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TALC (UNII: 7SEV7J4R1U)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, WHEAT (UNII: 79QS2MG2LP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:1) (UNII: 74G4R6TH13)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
STARCH, CORN (UNII: O8232NY3SJ)	
GELATIN (UNII: 2G86QN327L)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	S704
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	03/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/01/2018	

Labeler - Strive Pharmaceuticals Inc. (080028013)