MAXIMUM STRENGTH DAYTIME NIGHTTIME SINUS RELIEF- acetaminophen dextromethorphan hbr guaifenesin phenylephrine hcl and acetaminophen dextromethorphan hbr doxylamine succinate phenylephrine hcl
CVS Pharmacy, Inc.

630T CVS 69842-442 MAXIMUM STRENGTH DAYTIME NIGHTTIME SINUS RELIEF

DRUG FACTS

Active ingredients (in each softgel)
Daytime Sinus Relief
Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Active ingredients (in each softgel)
Nighttime Sinus Relief
Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Doxylamine succinate 6.25 mg
Phenylephrine HCl 5 mg

Purposes
Daytime Sinus Relief
Pain reliever
Cough suppressant
Expectorant
Nasal decongestant

Purposes
Nighttime Sinus Relief
Pain reliever
Cough suppressant
Antihistamine
Nasal decongestant

Uses
- temporarily relieves:

cough

minor aches and pains

headache
nasal congestion
sinus congestion and pressure
runny nose and sneezing (***Nighttime only***)
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive. (***Daytime***

only)
- temporarily promotes nasal and/or sinus drainage

WARNINGS

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
- more than 12 softgels in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen

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 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***)
- breathing problems 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 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**
- excitability may occur, especially in children (***Nighttime only***)
- marked drowsiness may occur (***Nighttime only***)
- alcohol, sedatives, and tranquilizers may increase drowsiness (***Nighttime only***)
- avoid alcoholic drinks (***Nighttime only***)

- be careful when driving a motor vehicle or operating machinery (***Nighttime only***)

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.
Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions
- **do not take more than directed (see Overdose warning)**
- do not take more than 12 softgels in any 24-hour period
- adults and children 12 years of age and older: take 2 softgels every 4 hours
- children under 12 years of age: do not use

OTHER INFORMATION

other information
- store at 20-25°C (68-77°F)
- avoid excessive heat

Inactive ingredients (Daytime only)
FD&C yellow no. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, shellac, sorbitol sorbitan solution, titanium dioxide, purified water.

Inactive ingredients (Nighttime only)
FD&C blue no. 1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, shellac, sorbitol sorbitan solution, titanium dioxide, purified water

***Questions?*call 1-877-290-4008**

MAXIMUM STRENGTH DAYTIME NIGHTTIME SINUS RELIEF

acetaminophen dextromethorphan hbr guaifenesin phenylephrine hcl and acetaminophen dextromethorphan hbr doxylamine succinate phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-442

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-442-24	1 in 1 CARTON	07/10/2021	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BLISTER PACK	16
Part 2	1 BLISTER PACK	8

Part 1 of 2

MAXIMUM STRENGTH DAYTIME SINUS RELIEF

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule, liquid filled

Product Information	
Item Code (Source)	NDC:69842-617
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics			
Color	orange	**Score**	no score
Shape	OVAL	**Size**	24mm
Flavor		**Imprint Code**	PC26
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69842-	16 in 1 BLISTER PACK; Type 0: Not a Combination		

1	617-16	Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/10/2021	

Part 2 of 2

MAXIMUM STRENGTH NIGHTTIME SINUS RELIEF

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl capsule, liquid filled

Product Information

Item Code (Source)	NDC:69842-290
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
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
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	green	**Score**	no score

Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	116
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-290-08	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	07/10/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	07/10/2021	

Labeler - CVS Pharmacy, Inc. (062312574)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(69842-442)

Revised: 2/2025 CVS Pharmacy, Inc.