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

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 final	part341	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 final	part341	07/10/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	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: 7/2021 CVS Pharmacy, Inc.