DAYTIME NIGHTTIME SINUS RELIEF MAXIMUM STRENGTH- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl/acetaminophen, dextromethorphan hbr, doxylamine succinate,phenylephrine hcl
Walgreens

Walgreens Sinus Relief Daytime Nighttime Cold & Flu

DRUG FACTS - Nighttime Sinus Relief

Nighttime Sinus Relief

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever

Cough suppressant

Antihistamine

Nasal decongestant

Uses

• temporarily relieves common cold/flu symptoms:
nasal congestion
headache
cough
minor aches and pains
sinus congestion and pressure
runny nose and sneezing
• 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
• with other drugs containing acetaminophen
• 3 or more alcoholic drinks daily 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 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 enlarged prostate gland
• glaucoma
• breathing problems such as emphysema or chronic bronchitis
• 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

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

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
• fever gets worse or lasts more than 3 days
• redness or swelling is present
• new symptoms occur
• cough comes back, or occurs with fever, 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 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 per 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

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

Inactive ingredients

FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Questions or Comments?

Call **1-877-290-4008**

DRUG FACTS - Daytime Sinus Relief

Active ingredients (in each softgel)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Purposes

Pain reliever
Cough suppressant
Expectorant
Nasal decongestant

Uses

• temporarily relieves common cold/flu symptoms:
nasal congestion
headache
cough
minor aches and pains
sinus congestion and pressure
• temporarily promotes nasal and/or sinus drainage
• helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

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

• with other drugs containing acetaminophen
• 3 or more alcoholic drinks daily 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 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 enlarged prostate gland
• 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

When using this product
• do not use more than directed

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
• fever gets worse or lasts more than 3 days
• redness or swelling is present
• new symptoms occur
• cough comes back, or occurs with fever, 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 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 per 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

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

Inactive ingredients

FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Questions or Comments?

Call **1-877-290-4008**

DAYTIME NIGHTTIME SINUS RELIEF MAXIMUM STRENGTH

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl/acetaminophen, dextromethorphan hbr, doxylamine succinate,phenylephrine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-0744

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0744-24	3 in 1 CARTON	06/01/2022	
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	4
Part 2	1 BLISTER PACK	8

Part 1 of 2

NIGHTTIME SINUS RELIEF MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hci capsule

Product Information	
Item Code (Source)	NDC:0363-0142
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	green	**Score**	no score
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	72
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 Drug	M012	06/01/2022	

Part 2 of 2

DAYTIME SINUS RELIEF MAXIMUM STRENGTH

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hci capsule

Product Information	
Item Code (Source)	NDC:0363-0145
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 HYDROCHLORIDE	5 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	**Score**	no score
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	78
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 Drug	M012	06/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/01/2022	

Labeler - Walgreens (008965063)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(0363-0744)

Revised: 3/2024

Walgreens