DAY-NIGHT SEVERE COLD AND FLU- day -acetaminophen, dextromethorhan hbr, guaifenesin, phenylephrine hcl night- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl,
RITE AID

627T Rite Aid 11822 8554 Severe Cold & Flu Relief 24 ct

DAYTIME COLD AND FLU

DAY SEVERE COLD AND FLU

Active ingredients (in each softgel)

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

Purposes

Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:

- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- minor aches & pains
- headache
- fever
- sore throat
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- 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 8 softgels 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.

Ask a doctor before use if you have
- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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
- you get nervous, dizzy or sleepless
- 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 rash or headache that lasts.

These could be signs of a serious condition.

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children. 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
- take only as directed
- do not exceed 8 softgels per 24 hrs

adults & children 12 yrs & over: 2 softgels with water every 4 hours.

children 4 to under 12 yrs: ask a doctor

children under 4 yrs: do not use

Other information

- do not exceed 25°C

Inactive ingredients

FD&C blue #1, FD&C red #40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

Questions or Comments?

call **1-877-290-4008**

NIGHTTIME COLD & FLU

NIGHT SEVERE COLD AND FLU

Active ingredients (in each softgel)

Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Doxylamine succinate 6.25 mg
Phenylephrine HCl 5 mg

Purposes

Pain reliever/fever reducer
Cough suppressant
Antihistamine
Nasal decongestant

Uses

temporarily relieves common cold/flu symptoms:
- nasal congestion
- sinus congestion & pressure
- cough due to minor throat & bronchial irritation
- cough to help you sleep
- minor aches & pains
- headache
- fever
- sore throat
- runny nose & sneezing
- reduces swelling of nasal passages
- temporarily restores freer breathing through the nose
- promotes nasal and/or sinus drainage

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take
- more than 8 softgels 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.

Ask a doctor before use if you have
- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to enlarged prostate gland

Ask a doctor or pharmacist before use if you are
- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

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

Stop use and ask a doctor if
- you get nervous, dizzy or sleepless
- 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 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 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

- take only as directed
- do not exceed 8 softgels per 24 hrs

adults & children 12 yrs & over: 2 softgels with water every 4 hrs.
children 4 to under 12 yrs: ask a doctor
children under 4 yrs: do not use

Other information

- do not exceed 25°C

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**

DAY-NIGHT SEVERE COLD AND FLU

day -acetaminophen, dextromethorhan hbr, guaifenesin, phenylephrine hcl night- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl, kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11822-8554

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-8554-0	1 in 1 BLISTER PACK; Type 0: Not a Combination Product	08/03/2020	

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

DAY SEVERE COLD AND FLU RELIEF

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

Product Information	
Item Code (Source)	NDC:11822-3854
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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL (UNII: 506T60A25R)	

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	orange	**Score**	no score
Shape	BULLET	**Size**	16mm
Flavor		**Imprint Code**	73
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-3854-9	16 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	08/03/2020	

Part 2 of 2

NIGHT SEVERE COLD AND FLU RELIEF

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

Product Information

Item Code (Source)	NDC:11822-3853
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)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	green	**Score**	no score
Shape	BULLET	**Size**	16mm
Flavor		**Imprint Code**	72
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-3853-8	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	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/03/2020	

Labeler - RITE AID (014578892)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LTD		925822975	manufacture(11822-8554)