DAY COLD AND FLU AND NIGHT SEVERE COLD AND FLU- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl, acetaminophen, dextromethorphan hbr, phenylephrine hcl, triprolidine hcl TARGET CORPORATION

-----

## Target Day Cold & Flu and Night Severe Cold & Flu Tablets

## **Drug Facts**

Active ingredients (in each caplet)
Day Cold & Flu
Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Active ingredients (in each caplet)
Night Severe Cold & Flu
Acetaminophen 325 mg
Dextromethorphan HBr 10 mg
Phenylephrine HCl 5 mg
Triprolidine HCl 1.25 mg

Purposes
Day Cold & Flu
Pain reliever/fever reducer
Cough suppressant
Expectorant
Nasal decongestant

Purposes
Night Severe Cold & Flu
Pain reliever/fever reducer
Cough suppressant
Nasal decongestant
Antihistamine

#### Uses

## Day Cold & Flu

temporarily relieves these common cold and flu symptoms:

- cough
- nasal congestion
- minor aches and pains
- sore throat
- headache
- stuffy nose
- sinus congestion and pressure

temporarily reduces fever

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

#### Night Severe Cold & Flu

temporarily relieves these common cold and flu symptoms:

- cough
- nasal congestion
- minor aches and pains
- sore throat
- headache
- sneezing
- sinus congestion and pressure
- runny nose
- itching of the nose or throat
- itchy, watery eyes due to hay fever

temporarily reduces fever controls cough to help you get to sleep

## Warnings

**Liver warning:**This product contains acetaminophen.

Severe liver damage may occur if you take:

- more than 4,000 mg 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.

**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
- diabetes
- high blood pressure
- thyroid disease
- glaucoma (Night Severe Cold & Flu only)
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis (Night Severe Cold & Flu 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 (Night Severe Cold & Flu only)

## When using this product

- do not use more than directed
- excitability may occur, especially in children (Night Severe Cold & Flu only)
- marked drowsiness may occur (Night Severe Cold & Flu only)
- alcohol, sedatives, and tranquilizers may increase drowsiness (Night Severe Cold & Flu only)
- avoid alcoholic drinks (Night Severe Cold & Flu only)
- use caution when driving a motor vehicle or operating machinery (Night Severe Cold & Flu 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
- 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**

## Day Cold & Flu

- do not take more than directed (see Overdose warning)
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years of age and over: take 2 caplets every 4 hours

• children under 12 years of age: do not use

#### Night Severe Cold & Flu

- do not take more than directed (see Overdose warning)
- do not take more than 8 caplets in any 24-hour period
- adults and children 12 years of age and over: take 2 caplets every 4 hours
- children under 12 years of age: do not use

#### Other information

store at 20-25°C (68-77°F)

#### Inactive ingredients Day Cold & Flu

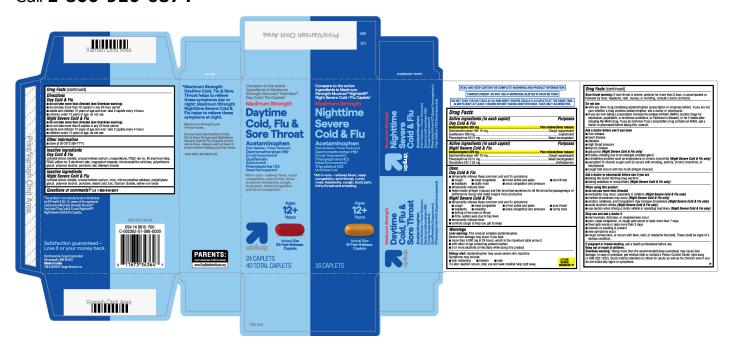
colloidal silicon dioxide, croscarmellose sodium, crospovidone, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, talc, titanium dioxide

## Inactive ingredients Night Severe Cold & Flu

colloidal silicon dioxide, croscarmellose sodium, mica, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, stearic acid, talc, titanium dioxide, yellow iron oxide

#### Questions or comments?

#### Call 1-800-910-6874



#### DAY COLD AND FLU AND NIGHT SEVERE COLD AND FLU

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl, acetaminophen, dextromethorphan hbr, phenylephrine hcl, triprolidine hcl kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-343

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:11673-343- 64	4 in 1 CARTON	05/01/2024		
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Quant	Quantity of Parts		
Part #	Package Quantity	Total Product Quantity	
Part 1	4 BLISTER PACK	24 in 6	
Part 2	4 BLISTER PACK	16 in 4	

# Part 1 of 2

## **DAY COLD AND FLU**

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, coated

Product Information	
Item Code (Source)	NDC:11673-347
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS 297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)

Product Characteristics				
Colorred (Light red to red)Scoreno score				
Shape	OVAL (Capsule shaped)	Size	19mm	
Flavor		Imprint Code	D1	
Contains				

	Pac	Packaging			
# Package Description				Marketing End Date	
	1		6 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	05/01/2024	

## Part 2 of 2

## **NIGHT SEVERE COLD AND FLU**

acetaminophen, dextromethorphan hbr, phenylephrine hcl, triprolidine hcl tablet, coated

# Product Information Item Code (Source) NDC:11673-792 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII: 2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	1.25 mg	

Inactive Ingredients	Ingredient Name	Strength
Inactive Ingredients		

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)

MICA (UNII: V8A1AW0880)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

STEARIC ACID (UNII: 4ELV7Z65AP)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics			
Color	yellow (Light golden yellow to Golden yellow)	Score	no score
Shape	OVAL (Capsule shaped)	Size	19mm
Flavor		Imprint Code	N1
Contains			

l	Pa	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	05/01/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/01/2024	

# Labeler - TARGET CORPORATION (006961700)

## **Registrant -** TIME CAP LABORATORIES, INC. (037052099)

Establishment			
Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(11673-343)

Revised: 8/2024 TARGET CORPORATION