MAXIMUM STRENGTH DAYTIME SEVERE AND NIGHTTIME COLD AND FLUdaytime- acetaminophen, dextromethorphan hbr, guaifenesin, nighttime acetaminophen, diphenhydramine hci TARGET Corporation

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748L Maximum Strength Daytime Severe Nighttime Cold & Flu (Without PE)

## Active ingredients for Nighttime (in each 20 mL)

#### Acetaminophen 650 mg

Diphenhydramine HCI 25 mg

Phenylephrine HCI 10 mg

## Active ingredients for Daytime (in each 20 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Guaifeenesin 400 mg

Phenylephrine HCl 10 mg

## **Purpose for Nighttime**

#### Pain reliever/fever reducer

Antihistamine/cough suppressant

Nasal decongestant

## **Purpose for Daytime**

Pain reliever / fever reducer

Cough suppressant

Expectorant

Nasal decongestant

#### Uses

## **Nighttime**

- temporarily relieves these common cold and flu symptoms
- cough
- nasal congestion
- minor aches and pains
- sore throat

- headache
- runny nose
- sneezing
- temporarily reduces fever
- controls cough to help you get to sleep

## **Daytime**

- temporarily relieves these common cold and flu symptoms
- cough
- nasal congestion
- minor aches and pains
- sore throat
- headache
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make cough more productive

## Warnings

#### **NIGHTTIME and DAYTIME**

**Liver warnin**g: This product contain acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- 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

## **Nighttime**

- with any drug containing acetaminophen (prescription or nonprescription) . If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other drug containing diphenhydramine, even one used on the skin
- 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
- for children under 12 years of age

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- for children under 12 years of age
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI)(certain drugs for depression,psychiatic 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

#### **Nighttime**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem 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)

## **Daytime**

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphtsema
- cough that occurs with too much phlegm (mucus)

## Ask a doctor or pharmacist before use if you are

## **Nighttime**

- you are taking the blood thinning drug warfarin
- you are taking sedative or tranquilizers

## **Daytime**

• taking the blood thinning drug warfarin

## When using these products

## **Nighttime**

- 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 vehicile or operating machinery

#### **Daytime**

do not use more than directed

#### Stop use and ask a doctor if

#### **Nighttime**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse, or lasts more than 7 days
- fever gets worse, or last 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 a signs of a serious condition

#### **Daytime**

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- 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,

## Nighttime and DayTime

ask a health professional before use.

## Keep out of reach of children.

## Nighttime and DayTime

**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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### **Directions**

## **Nighttime**

- do not take more than directed (see overdose warning)
- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- mL = mililiter
- dose as follows or as directed by a doctor

- adults and children 12 years and older: 20 mL every 4 hours while symptoms last
- children under 12 years of age: do not use

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- measure only with dosing cup provided. Do not use any other dosing device.
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- keep dosing cup with product
- mL = milliliter
- adults and children 12 years of age and older: 20 mL every 4 hours
- children under 12 years of age: do not use

#### Other information

## **Nighttime**

- each 20 mL contains: sodium 12 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

## **Daytime**

- each 20 mL contains: 12 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

## Inactive ingredients

## **Nighttime**

citric acid, disodium EDTA, FD&C Blue #1, FD&C red #40, Flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

## **Daytime**

citric acid, disodium EDTA, FD&C blue #1, FD&C red #40, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

## **Principal Display Panel**

#### **NIGHTTIME**

Compare to active ingredients in Maximum Strength Mucinex®Fast-Max® Night Time Cold & Flu\*\*

maximum strength

## nighttime

#### Cold & Flu

acetaminophen (pain reliever / fever reducer)

diphenhydramine HCI (antihistamine / cough suppressant)

phenylephrine HCI (nasal decongestant)

Relieves aches, fever, sore throat

controls cough

relieves nasal congestion

relieves runny nose and sneezing

AGES 12 + YEARS

#### **DAYTIME**

# Compare to active ingredients in Maximum Strength Mucinex® Fast-Max® Day Time Severe Cold\*

maximum strength

daytime

Severe Cold

acetaminophen (pain reliever / fever reducer)

dextromethorphan HBr (cough suppressant)

guaifenesin (expectorant)

phenylephrine HCI (nasal decongestant)

Relieves aches, fever & sore throat

Controls Cough

relieves nasal and chest congestion

thins and loosens mucus

AGES 12 + YEARS

# TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND OR UNDER CAP IS BROKEN OR MISSING.

\*This prodect is not manufactured or distributed by Recitt Benckiser, distributor of Maximum Strength Mucinex® Fast-Max® Day Time Severe Cold.

\*\*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® FAST-MAX® Night Time Cold & Flu.

Dist. by Target Corp.

Minneapolis, MN 55403

Product of U.S.A.

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Questions? Call 1-800-910-6874

#### **Product Label**



# MAXIMUM STRENGTH DAYTIME SEVERE AND NIGHTTIME COLD AND FLU

daytime- acetaminophen, dextromethorphan hbr, guaifenesin, nighttime - acetaminophen, diphenhydramine hci kit

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-794

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:11673-794- 01	1 in 1 KIT; Type 0: Not a Combination Product	05/01/2024	

Quant	Quantity of Parts			
Part #	Package Quantity	Total Product Quantity		
Part 1	1 BOTTLE, PLASTIC	177 mL		
Part 2	1 BOTTLE, PLASTIC	177 mL		

## Part 1 of 2

## **MAXIMUM STRENGTH DAYTIME SEVERE COLD**

acetaminophen, dextromethorphan hbr, guaifenesin liquid

Product Information	
Item Code (Source)	NDC:11673-709

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ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 20 mL	

Inactive Ingredients	
Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

l	Pa	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1		177 mL in 1 BOTTLE, PLASTIC; 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

## **MAXIMUM STRENGTH NIGHTTIME COLD AND FLU**

acetaminophen, diphenhydramine hci liquid

## **Product Information**

Item Code (Source)

NDC:11673-711

**Route of Administration** 

ORAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 20 mL		
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 20 mL		

Inactive Ingredients	
Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)	

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OTC Monograph Drug	M012	05/01/2024				

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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		677604129	manufacture(11673-794)				

Revised: 12/2023 TARGET Corporation